U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4261—4280

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *January 3, 1950.*

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*For presence of a habit-forming narcotic without warning statement, see Nos. 4264, 4265; omission of, or unsatisfactory, ingredients statements, Nos. 4263, 4264, 4273, 4275; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4264; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4264, 4267.

323789—55——1

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4261. Misbranding of vaginal suppositories. U. S. v. 138 Boxes * * * (and 1 other seizure action). (F. D. C. Nos. 36058, 36113. Sample Nos. 48093–L, 74278–L.)

LIBELS FILED: October 27 and November 17, 1953, Eastern District of Louisiana and Southern District of California.

ALLEGED SHIPMENT: On or about June 24, August 21, and October 5, 1953, by the Dr. J. A. McGill Co., from Chicago, Ill.

PRODUCT: 243 boxes of *vaginal suppositories* at New Orleans, La., and Los Angeles, Calif. Each box contained a copy of a leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

Examination showed that each suppository weighed approximately from 5.3 to 5.5 grams and contained approximately 47 percent ammonium alum.

LABEL, IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum – Borax – Petrolatum * * * Dr. J. A. McGill Co. * * * Chicago 16, Ill."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement appearing in the labeling of the article "For Simple Irritations Of The Vaginal Tract" was false and misleading. The statement represented and suggested that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract, whereas the article was not an adequate and effective treatment for these diseases.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil at bedtime, insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: December 9 and 14, 1953. Default decrees of condemnation and destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4262. Misbranding of thyroid tablets, Seconal Sodium capsules, capsules containing a mixture of Seconal Sodium and Amytal Sodium, and capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil. U. S. v. Center Drug Store of Durham, Inc., David G. Ridenhour, Verne D. Lea, and William A. Burwell. Pleas of guilty. Fine of $500 and probation for 2 years against corporation and $500 and probation for 2 years against Defendant Ridenhour; fine of $250 against Defendant Lea and $250 against Defendant Burwell. (F. D. C. No. 35166. Sample Nos. 59262–L, 59273–L, 59274–L, 59647–L, 59648–L, 59651–L.)

INFORMATION FILED: September 10, 1953, Middle District of North Carolina, against Center Drug Store of Durham, Inc., Durham, N. C., David G. Ridenhour, secretary-treasurer and manager of the corporation, and Verne D. Lea and William A. Burwell, pharmacists for the corporation.

NATURE OF CHARGE: On or about March 24 and April 9, 11, 14, and 15, 1953, while a number of *thyroid tablets*, *Seconal Sodium capsules*, *capsules containing a mixture of Seconal Sodium and Amytal Sodium*, and *capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil* were being held for sale at Center Drug Store of Durham, Inc., after shipment in interstate commerce, various quantities of the *Seconal Sodium capsules* and *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were dispensed upon requests for refills of written prescriptions for such drugs without obtaining authorization from the prescriber; and various quantities of the other drugs involved were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale. The corporation and Defendant Ridenhour were charged with causing the acts of dispensing involved in all counts of the information; Defendant Lea was included as a defendant with respect to the dispensing on April 14 of *capsules containing a mixture of Seconal Sodium and Amytal Sodium* and *capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil;* and Defendant Burwell was joined as a defendant with respect to the dispensing on April 9 of the *thyroid tablets*.

DISPOSITION: September 28, 1953. The defendants having entered pleas of guilty, the court fined the corporation $500, Defendant Ridenhour $500, Defendant Lea $250, and Defendant Burwell $250. The court also placed the corporation and Defendant Ridenhour on probation for 2 years.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4263. Misbranding of laxative herb tablets. U. S. v. 2 Drums, etc. (F. D. C. No. 35412. Sample No. 37516–L.)

LIBEL FILED: September 9, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about May 5, 8, and 20, 1953, by the Robin Pharmacal Corp., from Brooklyn, N. Y.

PRODUCT: 2 drums, each containing 22,500 tablets, and 9 drums, each containing 43,000 tablets, of *laxative herb tablets* at Newark, N. J., in possession of Miller Co., Inc., together with a number of leaflets entitled "This is the result of becoming thoroughly acquainted with J. Miller's Laxative Herb Compound #6."

RESULTS OF INVESTIGATION: The tablets contained in the drums were to be repackaged by the consignee into 250-tablet size packages. The leaflets were printed locally for the consignee.

LABEL, IN PART: (Drum) "Product Laxative Herb Tab."; (package) "J. Miller's Laxative Herb Compound No. 6 Pure Herbs 250 Tablets Active Ingredients: Senna and Frangula Inactive Ingredients: Triticum, Fennel, Gentian and Agar."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for sour stomach, gallbladder, liver, kidney, and urinary bladder trouble, rheumatic pains, arthritis, diabetes, and many other common ailments. The article was not an adequate and effective treatment for such

conditions. The article was misbranded in the above respect while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1) and (2), the labeling of the article failed to bear adequate directions for use and adequate warnings against use in those pathological conditions and by children where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users since the article was essentially a laxative and its labeling failed to bear adequate directions for use as a laxative and failed to warn against the use of the article when symptoms of appendicitis were present; and, Section 503 (b) (4), the labeling of the article bore the statement "Caution: Federal law prohibits dispensing without prescription," and the article was not subject to the provisions of Section 503 (b) (1). The article was misbranded in the above respects when introduced into and while in interstate commerce.

DISPOSITION: October 15, 1953. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4264. **Misbranding of phenobarbital tablets, thyroid tablets, anhydrohydroxyprogesterone tablets, dextro-amphetamine sulfate tablets, and tablets containing a mixture of mannitol hexanitrate and phenobarbital. U. S. v. Ken Reynolds Pharmacies, Inc., Kenneth R. Reynolds, and Walter J. Foohy. Pleas of nolo contendere. Fine of $300 against corporation and $250 against Kenneth R. Reynolds, plus costs. Sentence suspended against Walter J. Foohy.** (F. D. C. No. 33718. Sample Nos. 31208–L, 31209–L, 31211–L, 31329–L, 32503–L, 32504–L.)

INFORMATION FILED: October 4, 1952, Western District of Missouri, against Ken Reynolds Pharmacies, Inc., Joplin, Mo., Kenneth R. Reynolds, president, and Walter J. Foohy, a pharmacist for the corporation.

ALLEGED VIOLATION: On or about July 31, October 1 and 31, and November 2, 1951, while a number of *phenobarbital tablets, thyroid tablets, anhydrohydroxyprogesterone tablets, dextro-amphetamine sulfate tablets,* and *tablets containing a mixture of mannitol hexanitrate and phenobarbital* were being held for sale at Ken Reynolds Pharmacies, Inc., after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded. The corporation was charged with causing the acts of repacking and dispensing involved in each of the 6 counts of the information; Kenneth R. Reynolds was joined as a defendant in 5 of the counts; and Walter J. Foohy was joined as a defendant in 1 count.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

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*See also No. 4263; veterinary preparations, Nos. 4279, 4280.

Further misbranding, Section 502 (b) (1), the repackaged drugs other than the *anhydrohydroxyprogesterone tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor. Section 502 (d), the repackaged *phenobarbital tablets* and *tablets containing a mixture of mannitol hexanitrate and phenobarbital* contained a derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and such repackaged drugs failed to bear labels containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Section 502 (e) (1), the repackaged *thyroid tablets* failed to bear a label containing the common or usual name of the tablets; and, Section 502 (e) (2), the repackaged *dextro-amphetamine sulfate tablets* and *tablets containing a mixture of mannitol hexanitrate and phenobarbital* failed to bear a label containing the common or usual name of each active ingredient of such tablets.

DISPOSITION: May 28, 1953. The corporation and Kenneth R. Reynolds having entered pleas of nolo contendere, the court fined the corporation $300 and Kenneth R. Reynolds $250, plus costs. On May 17, 1954, Walter J. Foohy entered a plea of nolo contendere, and, on the same day, the court suspended the imposition of sentence against this defendant.

4265. Misbranding of quinine sulfate tablets and Chlorbrom syrup (bromide sedative). U. S. v. Chase Chemical Co. and Sydney Chasman. Plea of guilty entered by company to 5 counts of information; plea of guilty entered by individual to 1 count. Fine of $500 against each defendant. (F. D. C. No. 33773. Sample Nos. 6442–L, 23478–L.)

INFORMATION FILED: April 20, 1953, District of New Jersey, against the Chase Chemical Co., a corporation, Newark, N. J., and Sydney Chasman, president of the corporation.

ALLEGED SHIPMENT: On or about November 8, 1951, and March 5, 1952, from the State of New Jersey into the States of Connecticut and New York.

LABEL, IN PART: (Bottle) "Tablets Quinine Sulfate * * * 0.13 Gm. (2 gr.) Chase Chemical Company Pharmaceutical Chemists Newark, New Jersey" and "Syrup Chlorbrom * * * Bromide Sedative * * * Steel Pharmaceutical Co., Inc. Distributors New York, N. Y."

NATURE OF CHARGE: *Chlorbrom syrup.* Misbranding, Section 502 (a), the label of the article contained statements which represented and suggested that each 5 cc. of the article contained 3 grains of sodium bromide, 3 grains of potassium bromide, and 3 grains of ammonium bromide, a total of 9 grains of bromides, which statements were false and misleading since each 5 cc. of the article did not contain a total of 9 grains of bromides but did contain a lesser amount. Section 502 (d), the article contained chloral hydrate, a chemical derivative of chloral, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the article failed to bear the statement "Warning—May be habit forming" in juxtaposition with the declaration on the label of the name and quantity of such chemical derivative; and, further, the name and quantity of the chemical derivative and the statement "Warning—May be habit forming" were not displayed upon the main panel label of the article immediately following the name of the article on the main panel.

Quinine sulfate tablets. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which the article was intended.

The information alleged also that certain vitamin preparations were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 20793.

DISPOSITION: December 18, 1953. The corporation having entered a plea of guilty to the 5 counts of the information and the individual having entered a plea of guilty to the count in the information relating to the *quinine sulfate tablets*, the court imposed a fine of $500 against each defendant.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4266. Adulteration of dextro-amphetamine sulfate tablets. U. S. v. Ross-Whitney Corp. (Heart Pharmaceutical Co. of California), Louis M. Mills, and Robert C. Whitney. Pleas of nolo contendere. Fine of $200 against corporation and $100 against each individual. (F. D. C. No. 33774. Sample No. 26646–L.)

INFORMATION FILED: June 2, 1953, Southern District of California, against the Ross-Whitney Corp., trading as the Heart Pharmaceutical Co. of California, Los Angeles, Calif., Louis M. Mills, president, and Robert C. Whitney, secretary-treasurer of the corporation.

ALLEGED SHIPMENT: On or about November 1, 1951, from the State of California into the State of Pennsylvania.

LABEL, IN PART: (Bottle) "1000 Tablets Heart Brand Dexedrine (Dextro-Amphetamine Sulfate) 5 mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since each tablet was represented to contain 5 milligrams of dextro-amphetamine sulfate, whereas each tablet contained less than 5 milligrams of dextro-amphetamine sulfate.

DISPOSITION: January 25, 1954. The defendants having entered pleas of nolo contendere, the court fined the corporation $200 and each individual $100.

4267. Adulteration and misbranding of ear drops and misbranding of Vita-Malt, nose drops, aluminum hydroxide gel, pyrilamine maleate liquid, and pyrilamine maleate tablets. U. S. v. Kimball Drug Co. (Kimball Wholesale Drug Co.), and Horace W. Kimball. Pleas of nolo contendere. Fine of $200 against individual; imposition of sentence against corporation suspended. (F. D. C. No. 33750. Sample Nos. 18271–L to 18277–L, incl.)

INFORMATION FILED: June 10, 1953, District of Arizona, against the Kimball Drug Co., a corporation trading as the Kimball Wholesale Drug Co., Phoenix, Ariz., and Horace W. Kimball, president of the corporation.

ALLEGED VIOLATION: On or about May 7, 1951, the defendants received in interstate commerce, at Phoenix, Ariz., a number of bottles of *Vita-Malt* which was misbranded; and, on or about May 8, 1951, the defendants caused a number of the bottles of *Vita-Malt* to be delivered for pay to the Maricopa County Hospital, at Phoenix, Ariz., in purported fulfillment of a purchase order issued by Maricopa County through its board of supervisors.

In addition, between May 7 and June 13, 1951, while various quantities of *nose drops, ear drops, aluminum hydroxide gel, pyrilamine maleate liquid,* and

25-milligram and 50-milligram *pyrilamine maleate tablets* were being held for sale at the Kimball Wholesale Drug Co., after shipment in interstate commerce, the defendants caused the *aluminum hydroxide gel* to be repacked into labeled bottles and caused labels to be affixed to the drums containing the *pyrilamine maleate tablets* and to the bottles containing the other drugs involved, and then caused such labeled bottles and drums of the drugs to be delivered to the Maricopa County Hospital, at Phoenix, Ariz., in purported fulfillment of a purchase order issued by Maricopa County through its board of supervisors, which acts resulted in the drugs contained in the labeled bottles and drums being misbranded and the *ear drops* being adulterated.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the *ear drops* differed from that which it purported and was represented to possess in that it was represented to contain 1 percent phenol, whereas it contained 4.8 percent phenol.

Misbranding, Section 502 (a), the label statements "RC * * * Packaged By Contract For R & C Co., Nutley, N. J." and "R & C * * * Packed By Contract R & C Co., Nutley, N. J." displayed upon the bottles and drums containing the above-mentioned drugs were false and misleading. The statements represented and suggested and created the impression that the drugs were products of Reed & Carnrick, an acceptable drug firm listed in the "Call for Bids" on the furnishing of drugs to the Maricopa County Hospital issued by Maricopa County, whereas the drugs were not products of the firm of Reed & Carnrick but were products of another firm. Further misbranding, Section 502 (b) (1), the drugs failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, in that the name and address, "R & C Co., Nutley, N. J.," borne upon the labels of the drugs, were not the name and place of business of the manufacturer, packer, or distributor of the drugs.

DISPOSITION: June 15, 1953. The defendants having entered pleas of nolo contendere, the court fined Horace Kimball $200 and suspended the imposition of sentence against the corporation.

4268. Adulteration and misbranding of Livo Ferrum capsules. U. S. v. 2 Drums, etc. (F. D. C. No. 34926. Sample No. 49878–L.)

LIBEL FILED: April 7, 1953, Eastern District of New York.

ALLEGED SHIPMENT: On or about December 18, 1952, by Bergen Pharmacal Co., Inc., from Jersey City, N. J.

PRODUCT: 2 20,000-capsule drums and 1 10,000-capsule drum of *Livo Ferrum capsules* at Brooklyn, N. Y.

LABEL, IN PART: (Drum) "Livo Ferrum Capsules Each Capsule Contains: Ferrous Sulfate Exicc. 3⅗ gr. * * * Niacinamide 5 gr. Intended for use in the treatment of iron deficient and nutritional anemias. Adult dose: 2 capsules 4 times daily."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 3⅗ grains of ferrous sulfate exsiccated and 5 grains of niacinamide per capsule.

Misbranding, Section 502 (a), the label statement "Each Capsule Contains: Ferrous Sulfate Exicc. 3⅗ gr. * * * Niacinamide 5 gr." was false and misleading as applied to the product, which contained less than 3⅗ grains of ferrous sulfate exsiccated and 5 grains of niacinamide per capsule.

DISPOSITION: January 21, 1954. Default decree of condemnation and destruction.

4269. Adulteration and misbranding of Hemate Formula tablets. U. S. v. 32 Bottles, etc. (F. D. C. No. 35422. Sample No. 39988–L.)

LIBEL FILED: October 6, 1953, District of Arizona.

ALLEGED SHIPMENT: On or about April 17, May 15, June 11, and July 10, 1953, by Hemate Products, from New York, N. Y.

PRODUCT: 32 120-tablet bottles and 31 30-tablet bottles of *Hemate Formula tablets* at Phoenix, Ariz. Examination of the article showed deficiencies in vitamin B_1 ranging from 32 percent to 43 percent and deficiencies in vitamin C ranging from 78 percent to 89 percent.

LABEL, IN PART: (Bottle) "The Hemate Formula Three tablets (Daily Dose) contain: Vitamin B_1 (Thiamine Hydrochloride) . . . . 15 Mg. * * * Vitamin C (Ascorbic Acid) . . . . 150 Mg. * * * Three Hemate Formula Tablets provide 15 times the minimum adult daily requirement (MADR) of Vitamin B_1; 5 times the MADR of Vitamin C."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 15 milligrams of vitamin B_1 and 150 milligrams of vitamin C per three tablets.

Misbranding, Section 502 (a), the label statement "Three tablets * * * contain: Vitamin B_1 * * * 15 Mg. * * * Vitamin C * * * 150 Mg." was false and misleading as applied to the article, which contained less than 15 milligrams of vitamin B_1 and less than 150 milligrams of vitamin C per three tablets.

DISPOSITION: December 3, 1953. Default decree of condemnation and destruction.

4270. Adulteration and misbranding of a vitamin preparation. U. S. v. 140 Bottles * * *. (F. D. C. No. 36109. Sample No. 73607–L.)

LIBEL FILED: November 12, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about June 25, 1953, from Philadelphia, Pa.

PRODUCT: 140 bottles of a *vitamin preparation* at Trenton, N. J. Analysis showed that the product contained 20 percent of the declared amount of vitamin A and approximately 50 percent of the declared amount of vitamin D.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 5,000 U. S. P. units of vitamin A and 1,000 U. S. P. units of vitamin D per 4 tablespoonfuls.

Misbranding, Section 502 (a), the label statement "Daily Recommended Dose Will Afford: Vitamin A (1 M. D. R.) . . . . 5,000 U. S. P. Units Vitamin D (2½ M. D. R.) . . . . 1,000 U. S. P. Units" was false and misleading as applied to the article, which contained less than the declared amounts of vitamin A and vitamin D.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: December 11, 1953. Default decree of condemnation and destruction.

4271. Adulteration of halazone tablets. U. S. v. 244 Cases * * *. (F. D. C. No. 36170. Sample No. 52637–L.)

LIBEL FILED: December 7, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about November 28, 1951, by the City Chemical Corp., from Fort Lawton, Wash.

PRODUCT: 244 cases, each containing 300 bottles, of *halazone tablets* at Jersey City, N. J.

LABEL, IN PART: (Bottle) "100 Tablets (or 100 Water Purification Tablets) * * * Halazone N. N. R. Abbott * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium carbonate, sodium chloride and boric acid."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since the standard provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone, whereas the article contained less than 90 percent of the labeled amount of halazone.

DISPOSITION: January 15, 1954. Default decree of condemnation and destruction.

4272. Adulteration and misbranding of rubber prophylactics. U. S. v. 47 Gross * * *. (F. D. C. No. 35722. Sample No. 59472–L.)

LIBEL FILED: October 14, 1953, Northern District of Georgia.

ALLEGED SHIPMENT: On or about July 13, 1953, by the Chemical Latex Exchange, from Philadelphia, Pa.

PRODUCT: 47 gross of *rubber prophylactics* at Atlanta, Ga. Examination of 100 units showed that 16 were dried out and could not be unrolled, or were otherwise defective and unsuitable for use.

LABEL, IN PART: "Zenith Lubri-Pak."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "For the prevention of disease" were false and misleading as applied to the article, which was dried out and could not be unrolled or was otherwise defective.

DISPOSITION: December 1, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4273. Misbranding of Kolorok. U. S. v. 38 Bottles, etc. (F. D. C. No. 30401. Sample No. 92051–K.)

LIBEL FILED: January 29, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 12, 1950, from Bayfield, Colo.

PRODUCT: 38 bottles of *Kolorok* and 19 60-pound unlabeled bags of bulk material at Brooklyn, N. Y., in possession of Leon Cadore, together with a num-

*See also Nos. 4261, 4263, 4265, 4267–4270, 4272.

ber of booklets entitled "Kolorok An Amazing Natural Remedy Direct From the Laboratories of Nature Itself" and a number of window placards entitled "Health from Nature You'd be surprised," "Come in and ask about Kolorok Amazing Natural Remedy," and "Health from Nature Kolorok Offers real lasting relief."

RESULTS OF INVESTIGATION: The product was shipped in bulk from Bayfield, Colo., and, after its receipt by the consignee, a portion of the bulk material was repacked into bottles bearing the Kolorok label. The booklets and window placards described above were prepared locally for the consignee. Analysis of the product showed that it was largely a hydrated form of calcium sulfate known as gypsum.

LABEL, IN PART: (Bottle) "Kolorok * * * highly assimilable Calcium Oxide 45.10 Sulphur Trioxide 45.40 Distributed by Kolorok * * * New York City."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklets and placards accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for burns, scalds, wounds, and insect bites; reconditioning teeth and gums; preventing emotional upsets, muscular cramps, loss of teeth, allergic disturbances, sensitivity manifestations, and acute disease of the liver in pregnant and nursing women; stomach trouble, kidney and liver ailments, rheumatism, neuritis, arthritis, high blood pressure, eczema, preventing poor blood, soft flesh, weak bones, and hundreds of other serious ailments; stomach ulcers, indigestion, loss of appetite, neurasthenia, skin diseases, hemorrhoids, bad burns, all acid conditions, intestinal ulcers, liver and bowel troubles, and kidney ailments; and for restoring the organs of the body to working condition. The article was not an adequate and effective treatment for such conditions.

Further misbranding, Section 502 (e) (1), the label of the article failed to bear the common or usual name of the article, namely, gypsum.

The article was alleged to be misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 21, 1954. Leon Cadore, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for repackaging and/or relabeling for use either as an antacid or as a dusting powder, or for investigational use, under the supervision of the Food and Drug Administration.

4274. Misbranding of LeCuro blood medicine. U. S. v. 55 Bottles, etc. (F. D. C. No. 36098. Sample No. 14740–L.)

LIBEL FILED: November 10, 1953, District of Wyoming.

ALLEGED SHIPMENT: On or about February 22, 1951, by Amos LeCureaux, from Denver, Colo.

PRODUCT: 55 bottles of *LeCuro blood medicine* at Laramie, Wyo., together with a number of leaflets containing statements relating to the product and identified by the words "Medical analysis of ingredients used in LeCuro Blood Medicine."

LABEL, IN PART: (Bottle) "LeCuro Blood Medicine Ingredients: Extract of Humulus, Lupulus, Senna, Jalap, Ginger, Sodium Salicylate, Bismuth, and Tegosept P. Carminatives * * * Net Contents One Quart Amos LeCureaux Manufacturer."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the above-mentioned leaflets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for impure blood, stomach trouble, rheumatism, colds, sore throat, asthma, bronchitis, influenza, infected tonsils, arthritis, lumbago, sciatica, sores, eczema, poor appetite, nervousness, sleeplessness, run-down condition, nervous stomach, "asthmatics," colitis, spastic colon, ulcers, and all common sicknesses. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: November 20, 1953. Amos LeCureaux having executed an acceptance of service and authorization for taking a final decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

4275. Misbranding of Ber-Ex tablets. U. S. v. 66 Cartoned Bottles * * *. (F. D. C. No. 35384. Sample No. 20184–L.)

LIBEL FILED: August 13, 1953, Western District of Wisconsin.

ALLEGED SHIPMENT: On or about June 3, 1953, by Pan Pharmacals, Inc., from Buffalo, N. Y.

PRODUCT: 66 cartoned bottles of *Ber-Ex tablets* at Madison, Wis.

LABEL, IN PART: (Carton and bottle) "100 Ber-Ex * * * Tablets Succinate-Salicylate Oral Therapy * * * Active Ingredients: Calcium Succinate Acetylsalicylic Acid."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle and carton labels of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritic and rheumatic disorders, including osteoarthritis, rheumatoid arthritis, rheumatic fever, sciatica, gout, bursitis, fibrositis, neuritis, and myositis. The article was not an adequate and effective treatment for such conditions.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since acetylsalicylic acid is not the common or usual name for aspirin.

DISPOSITION: November 13, 1953. Default decree of condemnation and destruction.

4276. Misbranding of vaginal jelly. U. S. v. 38 Cartoned Tubes * * *. (F. D. C. No. 35418. Sample No. 47468–L.)

LIBEL FILED: September 4, 1953, Northern District of Alabama.

ALLEGED SHIPMENT: On or about June 15, 1953, by the Commonwealth Research Laboratories, from Grand Rapids, Mich.

PRODUCT: 38 cartoned tubes of *vaginal jelly* at Birmingham, Ala. Each carton of the product contained a copy of a leaflet entitled "Facts and Instructions Concerning 'Pru' a Bacteridicidal and Bacteriostatic Gel."

LABEL, IN PART: (Carton) "Pru The Family Antiseptic A non-toxic antiseptic jelly. Recommended for Feminine Cleanliness. Active Ingreidents: Oxyquinoline Sulphate, Boric Acid, Lactic Acid, Alum, Glycerine, Benzoic Acid, Gum Tragacanth. Net Contents 3 Ounces * * * For Feminine Hygiene."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "for Feminine Cleanliness" and "For Feminine Hygiene" were false and misleading since the article would not be effective for such purposes.

Further misbranding, Section 502 (a), certain statements in the above-mentioned leaflet were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for eczema, hemorrhoids, lacerations and ulcerated tissues of the cervix, trichomonas vaginitis, leucorrhea, vulvitis, and vaginitis. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: October 28, 1953. Default decree of condemnation and destruction.

4277. Misbranding of hormone liquid cleansing cream. U. S. v. 40 Cases, etc. (F. D. C. No. 34886. Sample No. 17403–L.)

LIBEL FILED: March 18, 1953, Southern District of California.

ALLEGED SHIPMENT: On or about December 26, 1952, by the Revlon Products Corp., from New York, N. Y.

PRODUCT: 40 cases, each containing 5 dozen plastic bottles, of *hormone liquid cleansing cream* at Los Angeles, Calif., together with a number of leaflets entitled "Introducing the Cosmetic Discovery of Your Lifetime."

Examination showed that the product consisted of a white, perfumed, oil-in-water creamy emulsion containing approximately 50 percent of mineral oil, 8 percent of saponifiable fats, 39 percent of water, with small proportions of other substances, including 0.65 milligram of estrogenic hormones per fluid ounce. Assay of the hormone content indicated that the label declaration "Contains 6,000 International Units Natural Estrogenic Hormones Per Ounce" was correct.

LABEL, IN PART: (Embossed on bottle) "'White Sable' Hormone Liquid Cleansing-Creme (Biologically Standardized) Revlon * * * Contains 6,000 International Units Natural Estrogenic Hormones Per Ounce. * * * Net Contents 6 Fl. Oz."; (gold tag tied to neck of each bottle) "Biologically Standardized 6,000 International Units Natural Estrogenic Hormones Per Ounce The First and Only Cleansing-Creme With Hormones!"

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label, on the tag tied to the neck of each bottle, and in the above-mentioned leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for rejuvenating the skin, replenishing the diminished estrogenic content of the tissues, providing the tissues instantly with hormones, and revitalizing mature, dehydrated skin. The article was not an adequate and effective treatment for such conditions and purposes.

DISPOSITION: January 15, 1954. The Revlon Products Corp. having appeared as claimant and without admitting or denying any of the allegations of the libel and having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the leaflets and the neck tags attached to the bottles be destroyed and that the product be delivered to charitable institutions.

4278. Misbranding of devices known as "Magnetic Affinitizer" and their accessories, assorted articles of drug, and various vitamin tablets. U. S. v. 4 Devices, etc. (F. D. C. No. 35270. Sample Nos. 43151–L to 43154–L,

incl., 43331–L to 43344–L, incl., 43346–L to 43364–L, incl., 43366–L to 43397–L, incl., 43399–L to 43402–L, incl., 43405–L to 43423–L, incl.)

LIBEL FILED: June 10, 1953, District of Nevada.

ALLEGED SHIPMENT: 3 devices were shipped by Seroyal Brands, Inc., from Orinda, Calif., to Reno, Nev., on a date subsequent to February 5, 1953; 1 device was purchased by a customer from a representative of Seroyal Brands, Inc., at Houston, Tex., and transported to Reno, Nev., on or about November 4, 1952. A set of 68 "cultures" was shipped with each device. In addition, assorted articles of drug and various vitamin tablets were shipped by Seroyal Brands, Inc., from Orinda, Calif., to Reno, Nev., during February and March 1953.

PRODUCT: 4 devices known as *Magnetic Affinitizer* and their accessories, the accessories consisting of a set of 68 "cultures," together with 2,000 bottles of *assorted articles of drug* and *various vitamin tablets* at Reno, Nev., and accompanying labeling consisting of the following printed and mimeographed matter: A collection of affidavits from users: Seroyal Brands bulletins numbered 2, 4, 12 ("Orinda Lucerne"), 12 ("Two New reflex points"), 19, 21, 23, 26, 33, 37, 38, 40, 41, 42, 51, 53, 54, 56, 57, and 59; reflex charts; "Doctor's Confidential Information (For investigational purposes)"; "Doctor's Confidential Information Food Combinations used per corresponding toxins"; bulletin by J. H. Wynkoop; "Orinda-Lucerne The 140 to 1 Concentrate"; "B–12 . . . 25 Micrograms * * * Case Report On Use of #1"; and copy of letter from Dr. Earl T. Walker.

The drugs and vitamin tablets were designated by various numbers, and they were represented in their labeling as containing certain ingredients as follows: *No. 1*—A mineral product, suspended in water, supplying silica, iron, aluminum, calcium, magnesium, and sulfur; *No. 2*—Vitamin B_{12} and dried liver substance tablets; *No. 3*—Vitamin B_{12} and duodenum substance tablets; *No. 4*—Fenugreek tea; *No. 5*—Assorted dehydrated vegetable tablets; *No. 6*—Vegetable tablets; *No. 7*—Vegetable tablets; *No. 8*—Protein hydrolysate; *No. 9*—Chlorophyll solution; *No. 10*—Vitamin C chlorophyll and queen of the meadow tablets; *No. 11-X*—Powdered alfalfa juice and chlorophyll tablets; *No. 12*—Alfalfa concentrate beverage base; *No. 13*—Turnip leaves juice concentrate tablets; *No. 14*—Queen of the meadow root; *No. 16*—Morning glory; *No. 17*—Black Walnut leaf; *No. 18*—Shave grass; *No. 19*—Vitamin B with chives; *No. 20*—Mineral water; *No. 21*—Vitamins C and E and rutin tablets; *No. 22*—Dehydrated mixed vegetables tablets; *No. 23*—Mixed dehydrated vegetables tablets; *No. 24*—Mixed dehydrated vegetables tablets; *No. 25*—Acidophilus, yeast, barley, hops, malt syrup, dextrose, levulose, rye, corn, tapioca and rice flours, and papain tablets; *No. 26*—Dehydrated mixed vegetables tablets; *No. 27*—Papain, glutamic acid hydrochloride, pepsin, and stomach substance tablets; *No. 28*—Vitamins A and D tablets; *No. 29*—Vitamin E tablets; *No. 30*—Vitamin E tablets; *No. 31*—Vitamin C tablets; *No. 32*—Vitamins A, B_1, B_2, C, and D, chlorophyll, yeast, turnip leaves, lettuce, spinach, beet leaves, watercress, and alfalfa tablets; *No. 33*—Papain tablets; *No. 34*—Dehydrated mixed vegetables tablets; *No. 36-F*—Unsaturated fatty acids and organically combined iodine; *No. 37*—Calcium carbonate, vitamin D, papain, and citric acid tablets; *No. 38*—Calcium carbonate (derived from egg shells) tablets; *No. 39*—Acidophilus, yeast, barley, hops, malt syrup, dextrose, levulose, rye, corn, and tapioca and rice flours; *No. 40*—Vitamin B_1 and ox bile extract tablets; *No. 41*—Solution of extractives from dulse and alfalfa; *No.*

42—Orthophosphoric acid and calcium phytate; *No. 43*—Yeast, egg calcium, and glucose tablets; *No. 44*—Vitamins B_1 and B_2 tablets; *No. 45*—Vitamin B_1 tablets; *No. 46*—Vitamin B_1 tablets; *No. 47*—Vitamins A, B_1, B_2, and C, and niacinamide and hydrolized proteins tablets; *No. 48*—Vitamins B_1 and C, iron tartrate, liver, stomach, hemoglobin, bone marrow, kelp, and yeast tablets; *No. 49*—Papain tablets; *No. 50*—Extract of garlic in oil capsules; *No. 51*—Vitamin A in odorless garlic, chlorophyll, and wheat germ oil capsules; *No. 52*—Vitamins A, B_1, C, and D, and chlorophyll tablets; *No. 53*—Russian radish, parsley, sugar beet extract, choline hydrochloride, and methionine tablets; *No. 54*—Cactus, betaine, and chlorophyll tablets; *No. 55*—Vitamin B_{12} concentrate tablets; *No. 56*—Yeast, skimmed milk, and soya meal tablets; *No. 57-X*—Duodenum substance tablets; *No. 59*—Chlorophyll tablets; *No. 81*—Mixed dehydrated vegetables tablets; *No. K-82*—Vegetable tablets; *No. D-83*—Vegetable tablets; *No. A-84*—Vegetable tablets; *No. S-85*—Vegetable tablets; *No. G-86*—Vegetable tablets; *No. R-87*—Dehydrated mixed vegetable tablets; *No. N-88*—Vegetable tablets; *No. V-90*—Vegetable tablets; *No. 91*—Clivers, buchu, juniper berries, couch grass, uva ursi, gravel root, stone root, cubebs, agrimony, dandelion, golden rod, and asparagus tablets; *No. U-92*—Dehydrated mixed vegetable tablets; *No. H-93*—Dehydrated mixed vegetable tablets; *No. W-96*—Rhubarb root and mixed vegetable tablets; *No. E-97*—Vegetable tablets; *No. 98*—Vegetables and vitamins A, B, C, D, and G tablets; *No. Y-100*—Vitamins A, B_1, C, D, and G, and vegetables and yeast tablets; *No. 101*—Yeast tablets; *No. 102*—Pumpkin seed, poke root, violet leaves, figwort herb, culvers root, myrrh gum, white oak bark, golden seal root, cascara sagrada bark, slippery elm bark, mandrake root, flax seed, comfrey root, mullein leaves, fenugreek seed, lobelia herb, pilewort herb, witch hazel bark, cranesbill root, and alfalfa tablets; *No. 103*—Mexican damiana leaves, Honduras sarsaparilla root, true cramp bark, squaw vine, black hawk bark of root, iodine (from kelp), ferrous gluconate, and copper gluconate tablets; *No. 104*—Mistletoe (berries, twigs, and leaves); *No. 105*—Papain kelp and chlorophyll tablets; *No. 106*—A solution of segments of the peel of citrus fruits, suspended in neutral oil; *No. 34-G*—Iodine and carbon derived from kelp and sea laminaria; *No. B-6*—Pyridoxine hydrochloride tablets; *vitamin A tablets; vitamin B complex tablets; vitamin D tablets with calcium and phosphorus; vitamin E tablets;* and *Vitamin G tablets with vitamin B_1 and niacin.*

Nature of Charge: *Magnetic Affinitizer.* Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device were false and misleading. The statements represented and suggested that the device was a valuable aid in determining nutritional deficiencies and body chemical balance, in better understanding of some symptoms, and as a supplement to other diagnostic measures; that it was useful as an aid in analyzing and determining the presence of toxins in the patient and in the selection of proper supplements for overcoming nutritional deficiencies; that it would increase the percentage of successful cures in chronic, active, and incipient cases; that it was effective to determine nerve pressure along the spinal column; that it would enable detection of disease before gross changes had occurred; that it would enable the detection of deficiencies of iodine and phosphorus; that it would enable the detection of food allergies; that, in one case, it demonstrated the presence of polio toxins; that vitamin C neutralized such toxins and that other vitamins were contraindicated; that, in another case, it demonstrated the presence of polio toxins and that vitamin C and other vitamins were contraindicated, and that a mineral formula and black walnut tea were indi-

cated to neutralize the toxin; that, in a third case of polio, it demonstrated that vitamin C was contraindicated, while vitamins A and D and calcium were indicated, enabling adequate treatment that prevented development of paralysis; that it would enable detection of arsenic in muscles and nerve tissue; that it would serve as a guide to enable successful treatment of cancer and polio; and that it would enable detection of flu in the heart, liver, and kidneys, strep infection in the lungs and other toxins in the body, cancer of the lungs, diabetes mellitus, copper in the lungs, aluminum intoxication, bursitis, excess or deficiency of hydrochloric acid in the stomach, infections, gallstones, gonorrhea, and inflammation of the colon. The device was not capable of fulfilling the promises of benefit made for it, and it would not accomplish the results stated and implied.

Assorted articles of drug and *various vitamin tablets.* Misbranding, Section 502 (a), certain statements in the accompanying labeling of such articles and tablets were false and misleading. The statements represented and suggested that the *assorted articles of drug* and the *various vitamin tablets* constituted adequate and effective treatments for disease conditions; that they would remedy infections and other affections of the body and parts thereof; and that each of the numbered articles of drug and the vitamin tablets would accomplish other results as follows:

No. 1—subclinical arthritis, soreness to the touch, tumor on cervix, tiredness, nervousness, irritability, hot flashes and other menopausal symptoms, asthma, kidney stone, swollen and inflamed bunions, palsy, sciatica, mumps, diphtheria, *Bacillus abortus*, gastric ulcer, relapsing fever, mastitis, fibroid tumor, sinusitis, allergy, sinus conditions, and multiple sclerosis;

No. 2—anemia, high or low white blood cells, low red blood count, rundown conditions, tired feeling, tuberculosis, and cancer;

No. 3—anemia, gastric ulcer, high or low white blood cells, intestinal irritation, low red blood count, stomach ulcers, tired feeling, ulcers, tuberculosis, cancer, and rundown conditions;

No. 4—mucous membrane, sinusitis, myel. leukemia, and lym. leukemia;

No. 5—hyperacidity;

No. 6—overalkalinity;

No. 7—overweight;

No. 8—chronic conditions in older people;

No. 9—anemias, arteriosclerosis, debility, nervousness, influenza, catarrh, hay fever, infections, sinusitis, Vincent's angina, and *Micrococcus catarrhalis;*

No. 10—anemias, arteriosclerosis, debility, nervousness, capillary fragility, lead poison, meningitis, contracted muscles, copper poison, polio, tetanus, poison sprays, tuberculosis, resistance to colds, influenza, diphtheria, diphtheroids, leukocytosis, pneumococcus, cancer, sarcina, multiple sclerosis, and colitis;

No. 11-X—anemias, arteriosclerosis, debility, nervousness, hyperacidity, meningitis, *Bacillus coli*, catarrh, *Endamoeba histolytica*, high or low white blood cells, infections, psoriasis, low red blood count, tetanus, pancreas, rheumatic fever, trypanosome, and white blood count;

No. 12—all over-acid conditions, asthma, blood sugar, resistance to colds, meningitis, *Bacillus coli*, typhoid bacillus, diphtheroids, leukocytosis, polio, psoriasis, low red blood count, sinusitis, diabetes, tularemia, pancreas, rheumatic fever, sarcina, trypanosome, myel. leukemia, lym. leu-

kemia, kidney stone, gallstones, colitis, familial jaundice, meningitis, and sinusitis;

No. 13—contraction of the bladder, frequent urination, crampy sensation in the pubic region, impaired digestion, puffiness, crampy pain during menstruation, nerve disorders, psoriasis, and skin;

No. 14—capillary fragility, contracted muscles, polio, tetanus, and multiple sclerosis;

No. 16—allergy asthma, cancer, fibroid tumor, syphilis, and internal growths;

No. 17—gonorrhea and malaria;

No. 18—burning bladder, nephritis, and trypanosome;

No. 19—allergies, hay fever, trichina, worms, trypanosome, tuberculosis, cancer, and multiple sclerosis;

No. 20—blood sugar and pancreas;

No. 21—high blood pressure, tuberculosis, resistance to colds, influenza, diphtheroids, leukocytosis, pneumococcus, cancer, heart, pain, and colitis;

No. 22—filariasis, colitis, *Salmonella pullorum*, trichina, worms, trypanosome, tapeworm, and intestinal infections;

No. 23—lead poison, copper poison, poison sprays, etc., and blood sugar;

No. 24—DDT poisoning, lead poison, copper poison, poison sprays, etc., and blood sugar;

No. 25—gallstones, kidney stones, tuberculosis, trypanosome, digestive disturbances, *Bacillus coli*, *Endamoeba histolytica*, colitis, Banti's disease, eczema squamous (dry scaly), eczema madidans (weeping), impetigo, alcoholic jaundice, amoeba, and multiple sclerosis;

No. 26—calcium metabolism, gallstones, gallbladder, bursitis, jaundice, liver function, kidney stones, and psoriasis;

No. 27—gallbladder;

No. 28—tuberculosis, pneumococcus, psoriasis, cancer, influenza, diphtheria, diphtheroids, staphylococci, gallstones, kidney stones, cirrhosis of the liver, and bursitis;

No. 29—heart, tuberculosis, cancer, and pain;

No. 30—heart, tuberculosis, cancer, and pain;

No. 31—resistance to colds, kidney stones, diphtheroids, jaundice, leukocytosis, pneumococcus, tuberculosis, influenza, diphtheria, cancer, alcoholic jaundice, familial jaundice, and colitis;

No. 32—anemias, arteriosclerosis, debility, nervousness, *Bacillus abortus* infection (undulant fever), asthma, bronchitis, resistance to colds, impetigo, nephritis, anthrax, pneumococcus, rundown conditions, tularemia, low vitality, relapsing fever, infections, rheumatic fever, influenza, diphtheria, diphtheroids, staphylococci, tuberculosis, cancer, leukocytosis, psoriasis, gonorrhea, ulcers, colitis, pain, *Micrococcus catarrhalis*, gastric ulcer, botulism, sinusitis, polyposis, Vincent's angina, filariasis, tetanus, cirrhosis of the liver, actinomycosis, bursitis, *Salmonella aertrycke* (chicken), chickenpox, measles, mumps, and colitis;

No. 33—asthma, typhoid bacillus, *Endamoeba histolytica*, and sarcina;

No. 34—anemias, arteriosclerosis, debility, nervousness, allergies, lead poison, copper poison, *typhoid*, bacillus poison sprays, etc., sarcina, blood infections, *Bacillus abortus*, and blood sugar;

No. 36-F—calcium metabolism, prostate, gallstones, kidney stones, skin, hair, nails, etc., psoriasis, cirrhosis of the liver, and bursitis;

No. 37—asthma, allergies, tuberculosis, hay fever, psoriasis, pneumococcus, cancer, cirrhosis of the liver, bursitis, and multiple sclerosis;

No. 38—asthma, tuberculosis, and allergies;

No. 39—overweight, underweight, squamous eczema, worms, trypanosome, tuberculosis bacillus, *Bacillus coli*, *Endamoeba histolytica*, colitis, Banti's disease, eczema madidans (weeping), impetigo, alcoholic jaundice, and amoeba;

No. 40—gallbladder, indigestion, cirrhosis of the liver, fatty liver, cancer, and tuberculosis;

No. 41—*Bacillus abortus* infection (undulant fever), actinomycosis, bronchitis, squamous eczema, impetigo, lead poison, anthrax, typhoid bacillus, cancer, copper poison, diphtheria, diphtheroids, *Endamoeba histolytica*, fibroid tumor, infections, cirrhosis of the liver, fatty liver, *Salmonella pullorum*, staphylococci, tularemia, polyposis, relapsing fever, sarcina, streptococci, syphilis, trypanosome, poison sprays, etc., Vincent's angina, toxin in endocrine gland, nervousness, asthma, eczema madidans (weeping), impetigo, and multiple sclerosis;

No. 42—calcification, gallstones, kidney stone, bursitis, cirrhosis of the liver, fatty liver, prostate, and psoriasis;

No. 43—asthma, allergies, constipation, digestion, squamous eczema, meningitis, nerves, hay fever, polio, trypanosome, muscles, digestive disturbances, and eczema madidans;

No. 44—tuberculosis, blood sugar, meningitis, heart, polio, pancreas, gonorrhea, diphtheria, ulcers, cancer, colitis, pain, and gastric ulcer;

No. 45—male gland, cancer, and tuberculosis;

No. 46—female gland, menopause, shrunken breasts, cancer, and tuberculosis;

No. 47—tuberculosis, resistance to colds, influenza, diphtheria, diphtheroids, leukocytosis, pneumococcus, cancer, gonorrhea, ulcers, colitis, pain, staphylococci, and gastric ulcer;

No. 48—Banti's disease, jaundice, low red blood count, rundown conditions, white blood count, tuberculosis, resistance to colds, influenza, diphtheria, diptheroids, leukocyosis, pneumococcus, cancer, colitis, and familial jaundice;

No. 49—gas, indigestion, and eczema squamous (dry scaly);

No. 50—filariasis, high blood pressure, colitis, heart, intestinal irritation, *Salmonella pullorum*, trichina, worms, stomach ulcers, tapeworm, and parasites;

No. 51—anemias, arteriosclerosis, debility, nervousness, *Bacillus abortus* infection (undulant fever), asthma, bronchitis, relapsing fever, influenza, diphtheria, diphtheroids, pneumococcus, stayphylococci, tuberculosis, cancer, and infections;

No. 52—common cold, streptococci, staphylococci, *Micrococcus catarrhalis*, *Bacillus abortus*, anthrax, tularemia, botulism, sinusitis, nephritis, polyposis, infectious mononucleosis, Vincent's angina, relapsing fever, filariasis, tetanus, influenza bacilli, impetigo, action mycosis, *Salmonella aertrycke* (chicken), chickenpox, measles, mumps, influenza, diphtheria, diphtheroids pneumococcus, staphylococci, tuberculosis, cancer, resistance to colds, leukocytosis, psoriasis, cirrhosis of the liver, bursitis, multiple sclerosis, and colitis;

No. 53—Banti's disease, kidney stone, gallbladder, jaundice, cirrhosis of the liver, fatty liver, gallstones, alcoholic jaundice, and familial jaundice;

No. 54—anemias, arteriosclerosis, debility, nervousness, blood sugar, menopause, heart, and pancreas;

No. 55—anemia, high or low white blood cells, rundown conditions, tuberculosis, tired feeling, and cancer;

No. 56—anemia, tuberculsis, jaundice, low red blood count, obesity, *Bacillus coli*, *Endamoeba histolytica*, colitis, Banti's disease, eczema squamous (dry scaly), eczema madidans (weeping), impetigo, and alcoholic jaundice;

No. 57-X—stomach ulcers and colitis;

No. 59—anemias, arteriosclerosis, debility, nervousness, actinomycosis, *Endamoeba histolytica*, infections, tetanus, rheumatic fever, *Micrococcus catarrhalis*, anthrax, tularemia, botulism, sinusitis, nephritis, polyposis, Vincent's angina, relapsing fever, filariasis, influenza bacilli, impetigo, *Salmonella aertrycke* (chicken), chickenpox, measles, and mumps;

No. 81—penicillin toxemias, *Bacillus abortus* infection (undulant fever), actinomycosis, gonorrhea, infectious mononucleosis, lead poison, malaria, nephritis, anthrax, cancer, copper poison, high or low white blood cell count, leukocytosis, staphylococci, tularemia, poison sprays, etc., relapsing fever, rheumatic fever, sarcina, streptococci, *Micrococcus catarrhalis*, myel. leukemia, lym. leukemia, erythrocytes, chickenpox, measles, and mumps;

No. K-82—calcification, kidney stone, and bursitis;

No. D-83—fibroid tumor, genitourinary irregularity, and polyposis;

No. A-84—hyperacidity, acid-alkaline imbalance, and overalkalinity;

No. S-95—bronchitis, sinusitis, polyposis, respiratory disturbances, and asthma;

No. G-86—colitis, ulcers, digestive disturbances, and gastric ulcer;

No. R-87—gonorrhea, infectious mononucleosis, malaria, low red blood count, staphylococci, poison sprays, etc., sarcina, streptococci, *Micrococcus catarrhalis*, myel. leukemia, lym. leukemia, anthrax, tularemia, rheumatic fever, nephritis, relapsing fever, leukocytes, actinomycosis, chickenpox, measles, and mumps;

No. N-88—nerve conditions, meningitis, nerves, bursitis, and nerve food;

No. V-90—loss of vigor, low vitality, tired feeling, and exhaustion;

No. 91—nephritis, kidneys, rheumatic fever, and hepatitis;

No. U-92—*Bacillus coli*, colitis, gastric ulcer, indigestion, intestinal irritation, putrefactions, stomach ulcers, and ulcers;

No. H-93—*Bacillus coli*, digestion, influenza, typhoid bacillus, colitis, worms, putrefactions, digestive putrefaction, indigestion, intestinal irritation, trichina, and tapeworm;

No. W-96—overweight and obesity;

No. E-97—high blood pressure;

No. 98—anemias, arteriosclerosis, debility, nervousness, *Bacillus abortus* infection (undulant fever), actinomycosis, squamous eczema, filariasis, influenza, malaria, nephritis, *Endamoeba histolytica*, infections, *Salmonella pullorum*, tetanus, tularemia, polyposis, relapsing fever, rheumatic fever, Vincent's angina, *Micrococcus catarrhalis*, botulism, sinusitis, eczema madidans (weeping), impetigo, chickenpox, measles, mumps, and poison oak;

No. F-99—allergies, tuberculosis, resistance to colds, influenza, cancer, rundown conditions, loss of vigor, low vitality, tired feeling, gonorrhea, colitis, diphtheria, diphtheroids, leukocytosis, pain, pneumococcus, psoriasis, staphylococci, gastric ulcer, cirrhosis of the liver, and bursitis;

No. Y-100—tuberculosis, resistance to colds, influenza, cancer, diphtheria, diphtheroids, pneumococcus, rundown conditions, loss of vigor, low vitality, tired feeling, gonorrhea, colitis, leukocytosis, pain, psoriasis, staphylococci,

ulcers, asthma, gastric ulcer, cirrhosis of the liver, bursitis, and multiple sclerosis;

No. 101—Bacillus coli, tuberculosis, squamous eczema, worms, *Endamoeba histolytica*, colitis, Banti's disease, eczema madidans (weeping), impetigo, alcoholic jaundice, and amoeba growths in the intestinal tract;

No. 102—internal parasites and multiple sclerosis;

No. 103—to impel the body to utilize metallic or foreign toxins and to increase vitality;

No. 104—epilepsy, convulsive nervous disorders, St. Vitus dance, cramps, flux, hysteria, dizziness, heart tonic, stitches in the side, ulcers, sores, worms, delayed menstruation, high blood pressure, and trouble of parturition;

No. 105—streptococci, staphylococci, *Endamoeba histolytica*, polio virus, and colitis;

No. 106—angina, calcification of the aorta, shortness of breath, heart pains, neuritis, painful testes, soreness or tenderness of testes, unusual hardness of testes, hemorrhoids, swelling over the thyroid area, skin cancer, frigidity, streptococcic sore throat, arthritis, falling hair, stiff knees, goiter, sore and inflamed eyes, prostate trouble, bursitis, "flu," swelling and soreness of glands in the groin, spastic condition of neck muscles, pain in soft tissue, streptococci, staphylococci, *Micrococcus catarrhalis*, sarcina, pneumococcus, gonococcus, cancer, polio virus, blood sugar, bronchitis, asthma, gastric ulcer, relapsing fever, hay fever, squamous eczema (dry scaly), madidans eczema (weeping), cirrhosis of the liver, influenza bacilli, smallpox, erythrocytes, leukocytes, familial jaundice, bursitis, mastitis, mumps, poison oak, burns, infectious sores, skin eruptions of long standing, thyroid, and growths of different kinds;

No. 34-G—stomach and intestines;

Vitamin B-6 tablets—bursitis, tuberculosis, cancer, and pain;

Vitamin A tablets—influenza, diphtheria, diphtheroids, pneumococcus, staphyloccci, tuberculosis, and cancer;

Vitamin B complex tablets—allergies, tuberculosis, and cancer;

Vitamin C tablets—tuberculosis, resistance to colds, influenza, diphtheria, diphtheroids, leukocytosis, pneumococcus, cancer, and colitis;

Vitamin D tablets with calcium and phosphorus—pneumococcus, psoriasis, tuberculosis, cancer, cirrhosis of the liver, and bursitis;

Vitamin E tablets—heart, tuberculosis, cancer, and pain;

Vitamin G tablets with vitamin B_1 and niacin—tuberculosis, gonorrhea, diphtheria, ulcers, cancer, colitis, pain, and gastric ulcer.

The above-mentioned *assorted articles of drug* and *various vitamin tablets* did not constitute adequate and effective treatments for the disease conditions mentioned; they would not remedy infections and other affections of the body and parts thereof; and they would not accomplish the results stated and implied.

DISPOSITION: September 3, 1953. Default decree of condemnation. The court ordered that the devices and 4 complete sets of the articles of drugs and vitamin tablets and their labeling be released to the Food and Drug Administration and that the remaining articles of drug and vitamin tablets be destroyed.

DRUGS FOR VETERINARY USE

4279. Misbranding of Dartol and Alatin. U. S. v. 27 Bottles, etc. (F. D. C. No 36202. Sample Nos. 83369-L, 83391-L.)

LIBEL FILED: December 22, 1953, Western District of Wisconsin.

ALLEGED SHIPMENT: On or about May 25 and October 2, 1953, by the Peerless Serum Co., from Kansas City, Mo.

PRODUCT: 27 1-pint bottles of *Dartol* and 33 1-pound jars and 6 5-pound jars of *Alatin* at Madison, Wis.

LABEL, IN PART: (Bottle) "Peerless Dartol 1 pint Each Ounce Contains Hexamethylenamine 60 gr. Color F. D. & C. Red No. 1 Indications For mild diarrhoeas in young suckling pigs"; (jar) "Alatin (With Nicotinic Acid) Poison * * * Contains: Sodium Hydroxide - - - 10% Nicotinic Sodium Thiosulphate Sodium Bicarbonate Copper Sulphate Methylene Blue Salt Oil Anise * * * Directions Dissolve one pound of Alatin in one gallon of water. Mix one pint of this solution to 15 gallons of water and soak feed over night. Allow no other drinking water during treatment."

NATURE OF CHARGE: *Dartol.* Misbranding, Section 502 (a), certain statements on the bottle label were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for diarrhea in suckling pigs, whereas it was not an adequate and effective treatment for diarrhea in suckling pigs.

Alatin. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the labeling failed to reveal the purposes and conditions for which the article was intended.

DISPOSITION: January 14, 1954. Default decree of condemnation and destruction.

4280. Misbranding of Testit white liniment. U. S. v. 127 Bottles, etc. (F. D. C. No. 36122. Sample No. 78760–L.)

LIBEL FILED: November 19, 1953, Eastern District of Kentucky.

ALLEGED SHIPMENT: On or about July 10, 1953, by the Peerless Serum Co., from Kansas City, Mo.

PRODUCT: 127 16-ounce bottles and 56 32-ounce bottles of *Testit white liniment* at Lexington, Ky.

LABEL, IN PART: (Bottle) "Testit White Liniment * * * Contains: Gum Camphor, Ammonia Chloride, Ammonia Water, and Turpentine in a soap base * * * A creamy white liniment for application to the skin surface. It may be used to advantage in sprains, inflammatory swellings of joints, tendon sheaths and glands. Also a stimulating lubricant for massage of the udder. This preparation may be used where ever or whenever a liniment is indicated."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for the conditions of sprains and inflammation of the joints, tendon sheaths, and glands of animals, whereas it was not an adequate and effective treatment for such conditions of animals.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use on the mucous membranes and in the area of the eyes and against continued use where the article would cause excessive irritation of the skin.

DISPOSITION: December 18, 1953. Default decree of condemnation and destruction.

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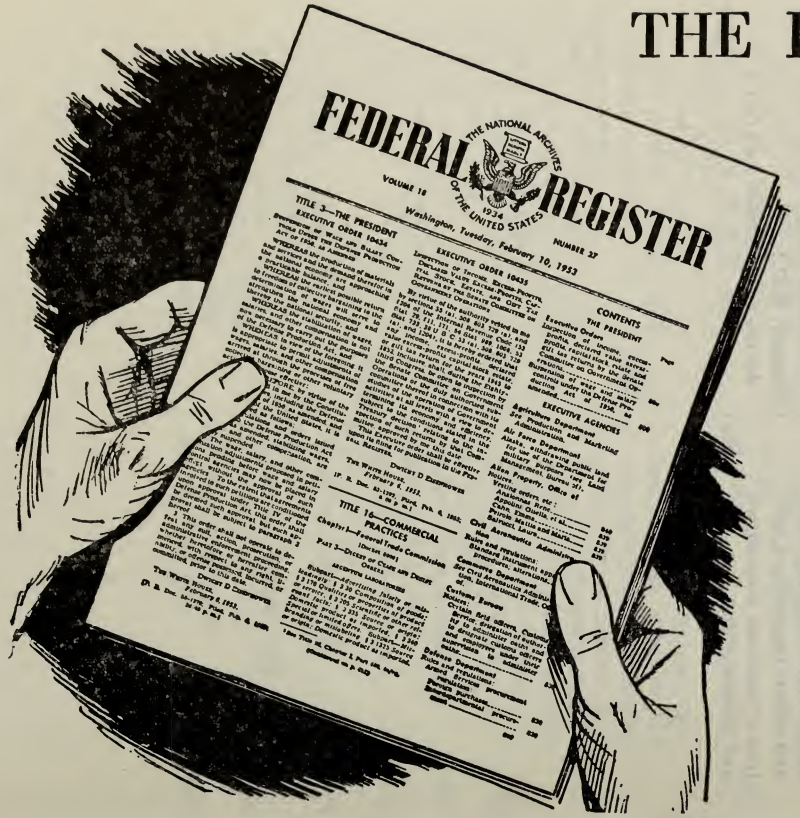

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J., F. D. C. 4281–4300 Issued February 1955

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4281–4300

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *February 11, 1955.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

4281. Misbranding of dextro-amphetamine sulfate tablets and methyltestosterone tablets. U. S. v. Frank L. Quinn (Quinn Pharmacy), and Byron F. Rowe. Pleas of guilty. Fine of $2,000 against Defendant Quinn and $300 against Defendant Rowe. Each defendant placed on probation for 3 years. (F. D. C. No. 35180. Sample Nos. 13261–L, 13263–L, 14701–L.)

INFORMATION FILED: October 27, 1953, District of Colorado, against Frank L. Quinn, trading as Quinn Pharmacy, Denver, Colo., and Byron F. Rowe, pharmacist.

NATURE OF CHARGE: On or about March 22 and 29 and April 8, 1953, while a number of *dextro-amphetamine sulfate tablets* and *methyltestosterone tablets* were being held for sale at the Quinn Pharmacy, after shipment in interstate commerce, various quantities of such drugs were dispensed upon requests for refills of written prescriptions therefor, without obtaining authorization from the prescriber. Defendant Quinn was charged with causing the dispensing of *dextro-amphetamine sulfate tablets* on March 29 and the dispensing of *methyltestosterone tablets* on April 8. Defendant Rowe was charged with causing the dispensing of *dextro-amphetamine sulfate tablets* on March 22. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: January 13, 1954. The defendants having entered pleas of guilty, the court fined Defendant Quinn $2,000 and Defendant Rowe $300 and placed each defendant on probation for 3 years.

4282. Misbranding of secobarbital sodium capsules, dextro-amphetamine sulfate tablets, methyltestosterone tablets, and pentobarbital sodium capsules. U. S. v. William N. Snider (South Denver Drug Co.), Max H. Metzner, and Norman Osborne, Jr. Pleas of guilty. Fine of $2,000 against Defendant Snider, $300 against Defendant Metzner, and $300 against Defendant Osborne. Defendants Snider and Osborne also placed on probation for 3 years. (F. D. C. No. 35175. Sample Nos. 14405–L, 69229–L, 69514–L, 69609–L.)

INFORMATION FILED: October 27, 1953, District of Colorado, against William N. Snider, trading as the South Denver Drug Co., Denver, Colo., and Max H. Metzner and Norman Osborne, Jr., pharmacists.

NATURE OF CHARGE: On April 14 and 18 and May 2 and 11, 1953, while a number of *secobarbital sodium capsules*, *dextro-amphetamine sulfate tablets*, and *pentobarbital sodium capsules* were being held for sale at the South Denver Drug Co., after shipment in interstate commerce, various quantities of the *secobarbital sodium capsules*, *dextro-amphetamine sulfate tablets*, and *pentobarbital sodium capsules* were dispensed upon requests for refills of written prescriptions for the drugs, without obtaining authorization from the prescriber, and a quantity of *methyltestosterone tablets* was dispensed without a prescription from a practitioner licensed by law to administed such drug. Defendant Snider was charged with causing the dispensing of the *secobarbital sodium capsules* and the *dextro-amphetamine sulfate tablets;* Defendant Metzner was charged with causing the dispensing of the *pentobarbital sodium capsules;* and Defendant Osborne was charged with causing the dispensing of the *methyltestosterone tablets*. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: January 13, 1954. The defendants having entered pleas of guilty, the court fined Defendant Snider $2,000, Defendant Metzner $300, and Defendant Osborne $300. The court also placed Defendants Snider and Osborne on probation for 3 years.

4283. Misbranding of Seconal Sodium capsules and dextro-amphetamine sulfate tablets. U. S. v. Carl T. Appel (Carl T. Appel Pharmacy). Plea of guilty. Fine of $600 and probation for 3 years. (F. D. C. No. 35148. Sample Nos. 20137–L, 20139–L, 20141–L, 64846–L.)

INFORMATION FILED: August 26, 1953, District of Minnesota, against Carl T. Appel, trading as the Carl T. Appel Pharmacy, Minneapolis, Minn.

NATURE OF CHARGE: On or about February 24 and March 1, 2, and 6, 1953, while a number of *Seconal Sodium capsules* and *dextro-amphetamine sulfate tablets* were being held for sale at the Carl T. Appel Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: December 4, 1953. The defendant having entered a plea of guilty, the court fined him $600 and placed him on probation for 3 years.

4284. Misbranding of sulfathiazole tablets, amphetamine sulfate tablets, and dextro-amphetamine sulfate tablets. U. S. v. Herman Steingold (Steingold Drugs). Plea of guilty. Fine of $500, plus costs. (F. D. C. No. 35154. Sample Nos. 33589–L to 33593–L, incl., 33595–L, 33596–L.)

INFORMATION FILED: August 28, 1953, Northern District of Illinois, against Herman Steingold, trading as Steingold Drugs, Chicago, Ill.

NATURE OF CHARGE: On or about February 24 and March 2, 5, 11, 18, and 22, 1952, while a number of *sulfathiazole tablets*, *amphetamine sulfate tablets*, and *dextro-amphetamine sulfate tablets* were being held for sale at Steingold Drugs, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: November 24, 1953. The defendant having entered a plea of guilty, the court fined him $500, plus costs.

4285. Misbranding of chloral hydrate capsules, amphetamine sulfate tablets, and Seconal Sodium capsules. U. S. v. William Melis. Plea of guilty. Sentence of 2 years in jail; sentence subsequently reduced to 1 year. (F. D. C. No. 35134. Sample Nos. 13822–L to 13824–L, incl., 14431–L to 14433–L, incl., 14436–L, 14437–L.)

INFORMATION FILED: August 19, 1953, District of Utah, against William Melis, manager of the City Pharmacy, Salt Lake City, Utah.

NATURE OF CHARGE: On or about February 24 and 28 and March 2, 3, and 5, 1953, while quantities of *chloral hydrate capsules*, *amphetamine sulfate tablets*, and *Seconal Sodium capsules* were being held for sale at the City Pharmacy, after shipment in interstate commerce, the defendant caused quantities of *Seconal Sodium capsules* to be dispensed upon requests for refills of a

written prescription, without obtaining authorization from the prescriber, and quantities of *chloral hydrate capsules* and *amphetamine sulfate tablets* to be dispensed without prescriptions therefor from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: December 4, 1953. The defendant having entered a plea of guilty, the court sentenced him to serve 2 years in jail. On December 18, 1953, the sentence was reduced to 1 year in jail.

4286. Misbranding of amphetamine sulfate tablets. U. S. v. Willard Green (Emerald Pharmacy). Plea of guilty. Fine of $600, plus costs. (F. D. C. No. 35155. Sample Nos. 33470–L, 33472–L, 33474–L to 33477–L, incl.)

INFORMATION FILED: September 11, 1953, Northern District of Illinois, against Willard Green, trading as Emerald Pharmacy, Chicago, Ill.

NATURE OF CHARGE: On or about January 14 and 20 and February 6, 12, and 16, 1953, while a number of *amphetamine sulfate tablets* were being held for sale at the Emerald Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: December 10, 1953. The defendant having entered a plea of guilty, the court fined him $600, plus costs.

4287. Misbranding of sulfadiazine tablets, tablets containing a mixture of phenobarbital, acetophenetidin, and acetylsalicylic acid, and tablets containing a mixture of sulfadiazine, sulfamerazine, sulfamethazine, and penicillin G potassium. U. S. v. Rollie D. Beckham (Beckham's Drug Store), and Tom L. Davidson. Pleas of guilty. Fine of $3 against Defendant Beckham and $1 against Defendant Davidson. (F. D. C. No. 35157. Sample Nos. 36684–L, 36685–L, 57116–L.)

INFORMATION FILED: October 2, 1953, Middle District of Tennessee, against Rollie D. Beckham, trading as Beckham's Drug Store, Lawrenceburg, Tenn., and Tom L. Davidson, a pharmacist.

NATURE OF CHARGE: On or about January 19 and 22 and February 28, 1953, while a number of *sulfadiazine tablets*, *tablets containing a mixture of phenobarbital, acetophenetidin, and acetylsalicylic acid*, and *tablets containing a mixture of sulfadiazine, sulfamerazine, sulfamethazine, and penicillin G potassium* were being held for sale at Beckham's Drug Store, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale. Rollie D. Beckham was charged with causing the acts of dispensing involved in each of the three counts of the information, and Tom L. Davidson was joined as a defendant in one of the counts.

DISPOSITION: November 17, 1953. The defendants having entered pleas of guilty, the court fined Defendant Beckham $3 and Defendant Davidson $1.

4288. Misbranding of sulfathiazole tablets and tablets containing a mixture of phenobarbital, acetophenetidin, aspirin, and caffeine. U. S. v. Lloyd Simpson (Palace Drug Store), and A. Wolff. Pleas of nolo contendere. Fine of $125 against each defendant. (F. D. C. No. 35174. Sample Nos. 61861–L to 61865–L, incl.)

INFORMATION FILED: October 22, 1953, Eastern District of Oklahoma, against Lloyd Simpson, trading as the Palace Drug Store, Hugo, Okla., and A. Wolff, pharmacist.

NATURE OF CHARGE: On or about May 6, 22, and 25, 1953, while a number of *sulfathiazole tablets* and *tablets containing a mixture of phenobarbital, acetophenetidin, aspirin, and caffeine* were being held for sale at the Palace Drug Store, after shipment in interstate commerce, the defendants caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: December 18, 1953. The defendants having entered pleas of nolo contendere, the court fined each defendant $125.

4289. Misbranding of sulfadiazine tablets and tablets containing a mixture of phenobarbital, acetophenetidin, aspirin, and caffeine. U. S. v. City Drug Store. Plea of nolo contendere. Fine, $150. (F. D. C. No. 35172. Sample Nos. 61851–L to 61856–L, incl.)

INFORMATION FILED: October 22, 1953, Eastern District of Oklahoma, against the City Drug Store, a partnership, Hugo, Okla.

NATURE OF CHARGE: On or about May 6, 19, 22, and 25, 1953, while a number of *sulfadiazine tablets* and *tablets containing a mixture of phenobarbital, acetophenetidin, aspirin, and caffeine* were being held for sale at the City Drug Store, after shipment in interstate commerce, the defendant caused various quantities of tablets to be dispensed without a prescription therefor from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: December 1, 1953. The defendant having entered a plea of nolo contendere, the court fined it $150.

4290. Misbranding of sulfadiazine tablets, ergonovine maleate tablets, and Seconal Sodium capsules. U. S. v. Shiro Drugs, Richard A. Shapiro, and Nathan Shapiro. Pleas of guilty. Fine of $100 against firm, $200 against Richard A. Shapiro, and $200 against Nathan Shapiro, plus costs. (F. D. C. No. 35183. Sample Nos. 58971–L, 58973–L to 58975–L, incl.)

INFORMATION FILED: October 29, 1953, Northern District of Illinois, against Shiro Drugs, a partnership, Chicago, Ill., and Richard A. Shapiro and Nathan Shapiro, partners in the partnership.

NATURE OF CHARGE: On or about March 4, 5, and 11, 1953, while a number of *sulfadiazine tablets, ergonovine maleate tablets,* and *Seconal Sodium capsules* were being held for sale at Shiro Drugs, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription therefor from a practitioner licensed by law to administer such drugs. The partnership was charged with causing the acts of dispensing involved in each of the 4 counts of the information, and Richard A. Shapiro was joined as a defend-

ant in counts 1 and 4 relating to the dispensing of the *sulfadiazine tablets* and Nathan Shapiro was joined as a defendant in the other counts of the information relating to the other drugs involved. The acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: November 30, 1953. The defendants having entered pleas of guilty, the court fined the partnership $100, Richard A. Shapiro $200, and Nathan Shapiro $200, plus costs.

4291. Misbranding of vinbarbital sodium capsules, pentobarbital sodium capsules, and capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil. U. S. v. Holland B. Leonard, Sr. (Leonard's Drug Store), and Holland B. Leonard, Jr. Pleas of guilty. Fine of $500 against Holland B. Leonard, Sr. Imposition of sentence suspended against Holland B. Leonard, Jr. (F. D. C. No. 35181. Sample Nos. 59085–L, 59086–L, 59090–L, 59644–L, 59649–L, 59650–L.)

INFORMATION FILED: During November 1953, Middle District of North Carolina, against Holland B. Leonard, Sr., trading as Leonard's Drug Store, High Point, N. C., and Holland B. Leonard, Jr., a pharmacist.

NATURE OF CHARGE: On or about April 8, 13, 14, 15, and 16, 1953, while a number of *vinbarbital sodium capsules, pentobarbital sodium capsules,* and *capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil* were being held for sale at Leonard's Drug Store, after shipment in interstate commerce, various quantities of *vinbarbital sodium capsules* and *pentobarbital sodium capsules* were dispensed upon requests for refills of written prescriptions therefor without authorization by the prescriber, and a quantity of *capsules containing a mixture of extract of ergot, apiol, and oil of savin in a vehicle of castor oil* were dispensed without a prescription from a practitioner licensed by law to administer such drug. Holland B. Leonard, Sr., was charged with causing the acts of dispensing involved in each of the 6 counts of the information, and Holland B. Leonard, Jr., was joined as a defendant in the third count of the information. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: December 7, 1953. The defendants having entered pleas of guilty, the court fined Holland B. Leonard, Sr., $500 and suspended the imposition of sentence against Holland B. Leonard, Jr.

DRUG ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4292. Misbranding of uranium ore. U. S. v. 6,000 Pounds, etc. (F. D. C. No. 36116. Sample No. 42770–L.)

LIBEL FILED: November 20, 1953, Northern District of California.

ALLEGED SHIPMENT: On or about August 25, 1953, by the Montana American Uranium Co., from Helena, Mont.

PRODUCT: 6,000 pounds of *uranium ore* at San Jose, Calif., in possession of Mr. W. B. Hewson of the Radium Radiation Health Center, together with a number of leaflets entitled "Radium Radiation Health Center" and a placard designated "Radium Radiation Health Treatment."

RESULTS OF INVESTIGATION: The above-mentioned leaflets were printed locally for the consignee for distribution to prospective patients, and the above-mentioned placard was on display in the window of the Radium Radiation Health Center.

The *uranium ore* was stored in bins lining the walls of a number of cubicles at the rear of the establishment. Each cubicle was provided with a bench or cot upon which the patient would lie while undergoing "treatment" provided by the purported radioactivity of the ore.

Examination showed that the total degree of radioactivity within the cubicles was not more than 0.24 milliroentgen per hour.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it did not state the disease conditions for which the article was intended, namely, arthritis, rheumatism, asthma, sinus conditions, lack of sleep, neuritis, skin disorders, bursitis, swollen joints, and ailments generally, and since the labeling did not, in fact, bear any directions for use.

DISPOSITION: December 1, 1953. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4293. Adulteration of a phenobarbital, bromide, and vitamin elixir. U. S. v. 24 Bottles, etc. (F. D. C. No. 35649. Sample No. 52615–L.)

LIBEL FILED: September 22, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about June 2, 1953, from Long Island City, N. Y.

PRODUCT: 24 1-pint bottles and 3 1-gallon bottles of a *phenobarbital, bromide, and vitamin elixir* at Irvington, N. J. Examination showed that the product was 80 percent deficient in riboflavin, 87 percent deficient in vitamin B_6, and 87 percent deficient in niacinamide.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that each 5 cc. (1 teaspoonful) of the article was represented to contain 0.5 milligram of vitamin B_2 (riboflavin), 3.0 milligrams of vitamin B_6, and 5.0 milligrams of niacinamide, whereas each 5 cc. (1 teaspoonful) of said drug contained less than 0.5 milligram of vitamin B_2 (riboflavin), less than 3.0 milligrams of vitamin B_6, and less than 5.0 milligrams of niacin. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: October 29, 1953. Default decree of condemnation and destruction.

4294. Adulteration and misbranding of amobarbital sodium capsules. U. S. v. 1 Drum * * *. (F. D. C. No. 35662. Sample No. 578–L.)

LIBEL FILED: September 30, 1953, Southern District of Indiana.

ALLEGED SHIPMENT: On or about July 1, 1953, by Wilson-Keith & Co., from St. Louis, Mo.

PRODUCT: 1 drum of *amobarbital sodium capsules* at Indianapolis, Ind. Examination showed that the product contained less than 73 percent of the declared amount of amobarbital sodium.

LABEL, IN PART: (Drum) "25,000 capsules Blue Interal Brand of Amobarbital Sodium U. S. P. 3 grains."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Amobarbital Sodium Capsules," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard. The standard provides that amobarbital sodium capsules contain not less than 90 percent of the labeled amount of amobarbital sodium, whereas the article contained less than 90 percent of the labeled amount of amobarbital sodium.

Misbranding, Section 502 (a), the label statement "Amobarbital Sodium U. S. P. 3 grains" was false and misleading as applied to the article, which contained less than 3 grains of amobarbital sodium per capsule.

DISPOSITION: October 22, 1953. The shipper and the consignee of the product having consented to the entry of a decree, judgment of forfeiture was entered and the court ordered that the product be destroyed.

4295. Adulteration and misbranding of Drilozets lozenges. U. S. v. 22 Bottles * * *. (F. D. C. No. 36074. Sample No. 73832–L.)

LIBEL FILED: October 27, 1953, District of New Jersey.

ALLEGED SHIPMENT: On an unknown date from Philadelphia, Pa.

PRODUCT: *Drilozets lozenges.* 22 bottles, each containing 48 lozenges, at Trenton, N. J. Analysis showed that the product contained less than 30 percent of the declared amount of polymyxin.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 2,500 units of polymyxin B sulfate per lozenge.

Misbranding, Section 502 (a), the label statement "Each 'Drilozet' contains polymyxin B sulfate, 2,500 units" was false and misleading as applied to the article, which contained less than 2,500 units of polymyxin B sulfate per lozenge.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 27, 1953. Default decree of condemnation and destruction.

4296. Adulteration and misbranding of adhesive bandages. U. S. v. 72 Boxes * * *. (F. D. C. No. 35719. Sample No. 54269–L.)

LIBEL FILED: October 14, 1953, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about July 15, 1953, by the Handy Pad Supply Co., from Worcester, Mass.

PRODUCT: 72 boxes of *adhesive bandages* at Detroit, Mich.

LABEL, IN PART: (Box) "100 Dandy Bandages 1" x 3¼" Plain — Borated Gauze Pad – Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive Bandage," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since the article was not sterile.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading as applied to the article, which was not sterile but was contaminated with living micro-organisms.

DISPOSITION: November 5, 1953. Default decree of condemnation and destruction.

4297. Adulteration and misbranding of adhesive strips. U. S. v. 198 Boxes * * *. (F. D. C. No. 35642. Sample No. 59467–L.)

LIBEL FILED: September 17, 1953, Middle District of North Carolina.

ALLEGED SHIPMENT: On or about August 11, 1953, by the Handy Pad Supply Co., from Worcester, Mass.

PRODUCT: 198 boxes of *adhesive strips* at Lexington, N. C.

LABEL, IN PART: (BOX) "100 Ideal Adhesive Strips 1" x 3¼" Sterilized * * * Southern First Aid Supply Co., Lexington, N. C."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Bandage," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since the article was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading.

DISPOSITION: November 9, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4298. Misbranding of Gramer's Sulgly-Minol. U. S. v. 138 Bottles, etc. (F. D. C. No. 36114. Sample No. 20107–L.)

LIBEL FILED: On or about November 9, 1953, District of Maryland.

ALLEGED SHIPMENT: On or about October 11, 1953, by the Walter W. Gramer Co., from Minneapolis, Minn.

PRODUCT: 138 bottles of *Gramer's Sulgly-Minol* at Bethesda, Md., together with a number of leaflets entitled "Gramer's Sulgly-Minol An Arthritis Treatment Of Outstanding Merit," "Gramer's Sulgly-Minol Sulphur Solution," and "Now Try Gramer's Sulgly-Minol."

LABEL, IN PART: (Bottle) "Gramer's Sulgly-Minol Contents 4 Fluid Ounces A solution of Sulphur, Glycerin, Sulphurated Lime and Alcohol 6%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the above-mentioned leaflets were false and misleading. The statements represented and suggested that the article, diluted with water and used as a foot bath, applied to the soles of the feet, or used as a tub bath, was an adequate and effective treatment for arthritis, rheumatism, and related ailments, and would prevent them; that it was an adequate and effective treatment for pains in the hips, legs, heels, ankles, joints of shoulders, arms, neck, back, and collarbone, and muscles in the back, legs, or feet; and that it was an adequate and effective treatment for boils and would purify the blood. The article, when used as directed, was not an adequate and effective treatment for such diseases and conditions, and it would not fulfill the promises of benefit stated and implied.

DISPOSITION: December 8, 1953. Default decree of condemnation and destruction.

*See also Nos. 4294–4297.

4299. **Misbranding of alfalfa tea. U. S. v. 36 Cans, etc.** (F. D. C. No. 35653. Sample No. 20445–L.)

LIBEL FILED: September 23, 1953, Southern District of Iowa.

ALLEGED SHIPMENT: On or about August 6, 1953, by the Werner Enterprises Co., from Minneapolis, Minn.

PRODUCT: 36 cans of *alfalfa tea* at Des Moines, Iowa, together with a number of leaflets entitled "Many Thousands are now using alfalfa (seed) tea as a treatment for rheumatoid arthritis." Examination showed that the product consisted of a mixture of seeds, predominantly alfalfa seed.

LABEL, IN PART: "Chlor-a-fal Alfalfa Tea 12 Ounces Net."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for rheumatoid arthritis, whereas the article was not an adequate and effective treatment for such condition.

DISPOSITION: October 23, 1953. Default decree of condemnation and destruction.

4300. **Misbranding of Atomotrone. U. S. v. 1 Device, etc.** (F. D. C. No. 36063. Sample No. 70051–L.)

LIBEL FILED: October 27, 1953, District of Colorado.

ALLEGED SHIPMENT: On or about September 2, 1953, by Charles A. Schnabel, from Austin, Tex.

PRODUCT: 1 device known as *Atomotrone*, at Pueblo, Colo., together with a leaflet entitled "Completing This Chart Places You Under No Obligation," a leaflet designated "Acidity Acne—I & E," and a leaflet entitled "Announcement Of The New Invention . . . the Atomotrone."

The device was a wood box containing a 275 watt sunlamp operated by household current, pieces of colored glass, and gallon glass jugs of water. The light from the sunlamp would shine through the colored glass on the water in the jugs, making the water in the jugs either "electric" if the glass was colored blue and purple, and "thermal" if the glass was colored red and amber. The "electric" water, the "thermal" water, and a combination of the "electric" water and the "thermal" water were to be used in the cure, mitigation, and treatment of various diseases.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above leaflets accompanying the device were false and misleading. The statements represented and suggested that the device was capable of providing an adequate and effective treatment for acidity, acne, Addison's disease, adenoids, ague, apoplexy, appendicitis, arthritis, asthma, bed-wetting, biliousness, bladder disease (cystitis), bloating, blood clot, blood poisoning, high blood pressure, boils, bronchitis, burns, cancer, carbuncles, catarrh, chickenpox, colds, spastic colon, convulsions, cramps in the limbs, cysts, dandruff, diabetes, diarrhea, dropsy, dysentery, dyspepsia, earache, eczema, epilepsy, xerophthalmia, fever, "flu," fungus infection, gas, high swollen glands, goiter, gonorrhea, gout, gums, hardening of the arteries, hard stool, hay fever, headache, migraine, heartburn, fast heart, hemorrhages, hemorrhoids, hiccough, painful indigestion, infections, itch, nephritis, Bright's disease, liver disease, leukemia, malaria, measles, meningitis, menopause difficulties, flooding, frequent or prolonged menstruation, milk leg, mumps, brittle nails, nervousness, neuralgia, neuritis, nosebleed, overweight, pain, palsy, pellagra, phlebitis, piles, pimples, pleurisy, pneumonia.

polio, prostate trouble, pyorrhea, rashes, rheumatic fever, rheumatism, ringworms, scarlet fever, sciatica, scurvy, shingles, sinus conditions, psoriasis, skin cancer, sleeplessness, running sores, stomach pain, syphilis, tapeworm, thyroid trouble, toxic condition, tuberculosis, typhoid fever, ulcers, uterus conditions, vomiting, whooping cough, inflamed womb, menstruation cramps, anemia, low blood pressure, cataract, chills, poor circulation, colds with much mucus, congested colon, constipation, emaciation, fainting, gallbladder, low glands, slow heart, congestive indigestion, stopped up intestines, delayed menopause, delayed menstruation, soft or no nails, rickets, sleeping sickness, sterility, congested stomach, teeth, weakness, abscess, congested circulation, deafness, debility, digestion, ear discharge, frigidity, gallstone, hernia, diseases of the heart such as angina pectoris, arteriosclerosis, coronary thrombosis, enlarged heart, irregular heart, leakage of the heart, jaundice, cirrhosis of the liver, pains during pregnancy and slow development of pregnancy, pus pocket, tonsils, tired feeling, tumors, varicose veins, and fallen womb. The device was not capable of providing an adequate and effective treatment for such conditions.

DISPOSITION: December 15, 1953. Default decree of condemnation. The court ordered that the device and the leaflets be turned over to the Food and Drug Administration.

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PRODUCTS

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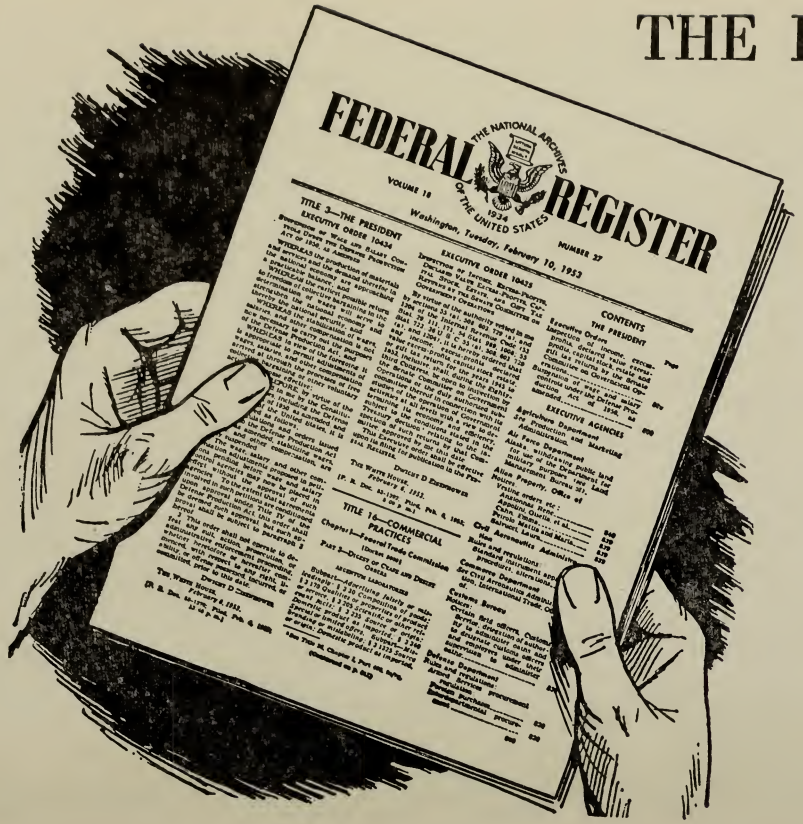

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D. D. N. J., F. D. C. 4301–4320

Issued March 1955

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4301–4320

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *February 18, 1950.*

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DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4301. Misbranding of vaginal suppositories. U. S. v. 22 Boxes * * *. (F. D. C. No. 36219. Sample No. 45306–L.)

LIBEL FILED: December 30, 1953. District of Rhode Island.

ALLEGED SHIPMENT: On or about July 3, 1953, by the Dr. J. A. McGill Co., from Chicago, Ill.

PRODUCT: 22 boxes of *vaginal suppositories* at Providence, R. I. Each box contained a copy of a leaflet entitled "Dr J. A. McGill Co.'s Suppositories." Examination showed that each suppository weighed approximately 5.47 grams and contained approximately 47 percent ammonium alum and 16 percent borax.

LABEL, IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum–Borax–Petrolatum * * * Dr. J. A. McGill Co. * * * Chicago 16, Ill."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement on the box label and in the above-mentioned leaflet, namely, "For Simple Irritations Of The Vaginal Tract," was false and misleading. The statement represented and suggested that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract, whereas the article was not an adequate and effective treatment for these diseases.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil at bedtime, insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: January 25, 1954. Default decree of condemnation and destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4302. Misbranding of secobarbital sodium capsules. U. S. v. Walter M. Risch (Walter's Drug Store). Plea of not guilty. Tried to the court and jury. Verdict of guilty. Defendant fined $2,500 and placed on probation for 2 years. (F. D. C. No. 35195. Sample Nos. 69251–L, 69262–L, 69272–L, 69276–L, 69282–L, 69291–L.)

INFORMATION FILED: October 27, 1953, District of Colorado, against Walter M. Risch, trading as Walter's Drug Store, Denver, Colo.

NATURE OF CHARGE: On or about November 12 and December 2 and 22, 1952, and January 2 and 16 and February 5, 1953, while a number of *secobarbital sodium capsules* were being held for sale at the Walter's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the capsules to be dispensed upon requests for refills of a written prescription therefor without obtaining authorization by the prescriber. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: The defendant entered a plea of not guilty on November 18, 1953. Thereafter, a motion for a bill of particulars was filed, and on February 11, 1954, this motion was denied. The case subsequently came on for trial before the court and jury, and on February 26, 1954, the jury returned a verdict of guilty. On March 24, 1954, the court fined the defendant $2,500 and placed him on probation for 2 years.

4303. Misbranding of penicillin G potassium tablets, sulfadiazine tablets, and secobarbital sodium capsules. U. S. v. Harold L. Potter (Potter's Drug Store), and Robert W. Lawson. Pleas of nolo contendere. Each defendant sentenced to 1 hour imprisonment; sentence suspended. (F. D. C. No. 35203. Sample Nos. 76141–L to 76144–L, incl.)

INFORMATION FILED: November 13, 1953, District of Idaho, against Harold L. Potter, trading as Potter's Drug Store, at Boise, Idaho, and Robert W. Lawson, an employee.

NATURE OF CHARGE: On or about June 25 and 29 and July 1, 1953, while a number of *penicillin G potassium tablets*, *sulfadiazine tablets*, and *secobarbital sodium capsules* were being held for sale at Potter's Drug Store, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Defendant Potter was charged with causing the acts of dispensing involved in each of the 4 counts of the information, and Defendant Lawson was joined as a defendant in 2 counts. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: February 8, 1954. The defendants having entered pleas of nolo contendere, the court imposed a sentence of 1 hour imprisonment against each defendant, but suspended this sentence.

4304. Misbranding of sulfathiazole tablets. U. S. v. Scott-Butler Drug Store, a partnership, Harry W. Scott, and Mayo Holman. Pleas of nolo contendere. Fine of $75 against Defendant Scott and $50 against Defendant Holman. Proceedings against partnership dismissed. (F. D. C. No. 35170. Sample Nos. 61882–L to 61884–L, incl.)

INFORMATION FILED: October 22, 1953, Eastern District of Oklahoma, against the Scott-Butler Drug Store, a partnership, Idabel, Okla., Harry W. Scott, a partner and manager of the partnership, and Mayo Holman, an employee of the partnership.

NATURE OF CHARGE: On or about May 19 and 22 and June 1, 1953, while a number of *sulfathiazole tablets* were being held for sale at the Scott-Butler Drug Store, after shipment in interstate commerce, various quantities of the tablets were dispensed without a prescription from a practitioner licensed by law to administer such drug. The partnership and Defendant Scott were charged with causing the acts of dispensing involved in each of the 3 counts of the information, and Defendant Holman was joined as a defendant in 2 counts. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed tablets being misbranded while held for sale.

DISPOSITION: February 19, 1954. Pleas of nolo contendere having been entered by the defendants, the court fined Defendant Scott $75 and Defendant Holman $50 and dismissed the proceedings against the partnership.

4305. Misbranding of sulfathiazole tablets. U. S. v. Paul R. Keiser (Paul R. Keiser, Pharmacist). Plea of guilty. Fine, $480. (F. D. C. No. 35202. Sample Nos. 66966–L, 66970–L, 66973–L.)

INFORMATION FILED: November 6, 1953, Eastern District of Pennsylvania, against Paul R. Keiser, trading as Paul R. Keiser, Pharmacist, Reading, Pa.

NATURE OF CHARGE: On or about June 9, 12, and 18, 1953, while a number of *sulfathiazole tablets* were being held for sale at the defendant's store, after shipment in interstate commerce, the defendant caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: February 2, 1954. The defendant having entered a plea of guilty, the court fined him $480.

4306. Misbranding of sulfathiazole tablets, sulfisoxazole tablets, and tablets containing a mixture of phenobarbital, acetophenetidin, aspirin, and caffeine. U. S. v. Palace Drug Store, Inc., William R. Anderson, and Johnnie G. Anderson. Pleas of nolo contendere. Fine of $75 against William R. Anderson and $50 against Johnnie G. Anderson; proceedings against corporation dismissed. (F. D. C. No. 35171. Sample Nos. 61891–L to 61895–L, incl.)

INFORMATION FILED: October 22, 1953, Eastern District of Oklahoma, against Palace Drug Store, Inc., Idabel, Okla., William R. Anderson, president of the corporation, and Johnnie G. Anderson, secretary-treasurer of the corporation.

NATURE OF CHARGE: On or about May 6, 19, 22, and 26, 1953, while a number of *sulfathiazole tablets*, *sulfisoxazole tablets*, and *tablets containing a mixture of phenobarbital, acetophenetidin, aspirin, and caffeine* were being held for sale at Palace Drug Store, Inc., after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. The corporation was charged with causing the acts of dispensing involved in each of the 5 counts of the information; William R. Anderson was joined as a defendant in 3 counts; and Johnnie G. Anderson was joined as a defendant in 2 counts of the information. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: February 19, 1954. Pleas of nolo contendere having been entered, the court fined William R. Anderson $75 and Johnnie G. Anderson $50 and dismissed the proceedings against the corporation.

4307. Misbranding of sulfathiazole tablets and dextro-amphetamine sulfate tablets. U. S. v. Robert E. Whiteman (Whiteman's Drug Store), and Albert C. Hooks. Pleas of nolo contendere. Fine of $100 against Defendant Whiteman and $50 against Defendant Hooks. (F. D. C. No. 35169. Sample Nos. 61871–L to 61874–L, incl.)

INFORMATION FILED: October 22, 1953, Eastern District of Oklahoma, against Robert E. Whiteman, trading as Whiteman's Drug Store, Idabel, Okla., and Albert C. Hooks, an employee in the store.

NATURE OF CHARGE: On or about May 6, 19, and 22, 1953, while a number of *sulfathiazole tablets* and *dextro-amphetamine sulfate tablets* were being held for sale at Whiteman's Drug Store, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Defendant Whiteman was charged with causing the dispensing of the drugs involved in each of the four counts of the information, and Defendant Hooks was joined as a defendant in two counts. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: February 19, 1954. The defendants having entered pleas of nolo contendere, the court fined Defendant Whiteman $100 and Defendant Hooks $50.

4308. Misbranding of dextro-amphetamine sulfate tablets, sulfathiazole tablets, and phenobarbital tablets. U. S. v. Corner Drug Co. Plea of guilty. Fine of $200, plus costs. (F. D. C. No. 34816. Sample Nos. 46579–L to 46583–L, incl.)

INFORMATION FILED: May 13, 1953, Northern District of Alabama, against the Corner Drug Co., a corporation, Florence, Ala.

NATURE OF CHARGE: On or about August 12, 13, 14, and 15, 1952, while a number of *dextro-amphetamine sulfate tablets*, *sulfathiazole tablets*, and *phenobarbital tablets* were being held for sale at the Corner Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: March 22, 1954. The defendant having entered a plea of guilty, the court fined it $200, plus costs.

4309. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Albert R. Barnett and Vernon B. Crittendon. Pleas of guilty. Each defendant fined $150, plus costs. (F. D. C. No. 34828. Sample Nos. 46571–L, 46574–L.)

INFORMATION FILED: May 13, 1953, Northern District of Alabama, against Albert R. Barnett, pharmacist for the North Florence Drug Co., Florence, Ala., and against Vernon B. Crittendon, a clerk for the company.

NATURE OF CHARGE: On or about August 12 and 15, 1952, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at the North Florence Drug Co., after shipment in interstate commerce, various quantities of the drug were dispensed without a prescription from a practitioner licensed by law to administer such drug. Defendant Barnett was charged with causing the act of dispensing involved in one of the two counts of the information, and Defendant Crittendon was charged with causing the act of dispensing involved in the other count. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: March 22, 1954. The defendants having entered pleas of guilty, the court fined each defendant $150, plus costs.

4310. Misbranding of dl-desoxyephedrine HCl tablets and amphetamine sulfate tablets. U. S. v. Woodard Roberts Mitchell. Plea of not guilty. Tried to the court. Verdict of guilty. Fine of $100 and imprisonment for 1 year on each of 3 counts of indictment; prison sentence suspended and defendant placed on probation for 5 years. (F. D. C. No. 35127. Sample Nos. 61166–L, 61169–L, 61170–L.)

INDICTMENT RETURNED: October 6, 1953, Western District of Oklahoma, against Woodard Roberts Mitchell, pharmacist and manager of the K & W Drug, Oklahoma City, Okla.

NATURE OF CHARGE: On or about January 21, 1953, while a number of *dl-desoxyephedrine HCl tablets* and *amphetamine sulfate tablets* were being held for sale at the K & W Drug, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: The defendant having entered a plea of not guilty, the case came on for trial before the court without a jury, and on January 27, 1954, the trial was concluded with the return of a verdict of guilty. On March 10, 1954, the court imposed a fine of $100 and imprisonment of 1 year on each of the 3 counts of the indictment, but suspended the prison sentence and placed the defendant on probation for 5 years.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4311. Misbranding of ACC capsules. U. S. v. 228 Bottles * * *. (F. D. C. No. 36187. Sample No. 62762–L.)

LIBEL FILED: December 15, 1953, Western District of Tennessee.

ALLEGED SHIPMENT: On or about August 11 and 19, 1953, from Portland, Ind.

PRODUCT: 228 100-capsule bottles of *ACC capsules* at Memphis, Tenn., in possession of the Pantaze Drug Stores.

RESULTS OF INVESTIGATION: In the October 19, 1953, issue of a local Memphis newspaper there appeared above the name of the dealer an advertisement for *ACC capsules.*

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in providing relief from the tortures of arthritis and rheumatic pains, which were the conditions and purposes for which the drug was recommended in the October 19, 1953, issue of a Memphis newspaper. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 27, 1954. Default decree of condemnation and destruction.

4312. Misbranding of ovarian substance desiccated powder. U. S. v. 23 Bottles, etc. (F. D. C. No. 36223. Sample No. 62209–L.)

LIBEL FILED: January 5, 1954, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about April 3, August 12, October 2, and November 16, 1953, from Chicago, Ill., and Omaha, Nebr.

PRODUCT: 23 1-ounce bottles, 2 4-ounce bottles, and 1 16-ounce bottle of *ovarian substance desiccated powder* at St. Louis, Mo., in possession of Narco Drug Co., Inc.

RESULTS OF INVESTIGATION: The product was shipped in bulk to St. Louis, Mo., and after its arrival there, was repackaged and relabeled upon instructions of Narco Drug Co., Inc.

LABEL, IN PART: (Bottle) "Narco * * * Ovarian Substance Desiccated * * * Caution: To be dispensed only by or on the prescription of a physician. Distributed by Narco Drug Co., Inc."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the repackaged article failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: February 2, 1954. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

4313. Misbranding of Indian Arrow herb preparation. U. S. v. Indian Arrow Herb Products Co., Pedro W. Whitson, and Ruth Whitson. Pleas of guilty entered by individuals. Fine of $100 against each individual; no sentence imposed against company. (F. D. C. No. 35563. Sample No. 66031–L.)

INFORMATION FILED: December 22, 1953, Southern District of Ohio, against the Indian Arrow Herb Products Co., a partnership, and Pedro W. Whitson and Ruth Whitson, partners in the partnership.

ALLEGED SHIPMENT: On or about February 6, 1953, from the State of Ohio into the State of Illinois.

LABEL, IN PART: (Bottle) "Indian Arrow Herb Preparation Laxative Stomachic Contains the following active herb ingredients: Mayapple Root, Cascara Segrada Bark, Blacksnake Root, Bitter Root, Wild Cherry Bark, White Ash Bark, Wahoo Bark, Chamomille Herb, with Sarsaparilla Root, Elm Bark, Sugar, Caramel added for flavor and color and water * * * Contents 8 Fluid Ounces Prepared By Indian Arrow Herb Products Company P. W. Whitson, Herbalist 1559 Central Ave. Cincinnati (14), Ohio."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article, consisting of a letter dated February 12, 1953, were false and misleading. The statements represented and suggested that the article would be an adequate and effective treatment for all forms of rheumatics, tuberculosis, blood disorders, kidney and liver afflictions, syphilis, and tumors. The article would not be an adequate and effective treatment for such diseases and conditions.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of the diseases and conditions for which the article was intended, namely, for all forms of rheumatics, tuberculosis, blood disorders, kidney and liver afflictions, syphilis, and tumors.

DISPOSITION: January 18, 1954. The individual defendants having entered pleas of guilty, the court imposed a fine of $100 against each individual, but imposed no sentence against the partnership.

4314. Misbranding of rubber diaphragms. U. S. v. 166 Devices * * *. (F. D. C. No. 35680. Sample No. 55178–L.)

LIBEL FILED: October 1, 1953, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about August 25, 1953, by Hychex Products, from Chicago, Ill.

PRODUCT: 166 devices, consisting of *rubber diaphragms*, contraceptive type, each of which was contained in a cardboard box, at Milwaukee, Wis.

RESULTS OF INVESTIGATION: The device was a prescription device, and its label did not bear the legend "Caution Federal Law Restricts This Device To Sale By or On The Order of a Physician." Further, the device was not restricted by the dealer to sale by or on the order of a physician.

LABEL, IN PART: (Box Cover) "PreCare Mensinga Diaphragm."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use.

DISPOSITION: January 27, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4315. Adulteration and misbranding of testosterone, Lynntestro, and estrone. U. S. v. Milton A. Calesnick (Addison Laboratories). Plea of guilty. Defendant fined $300 and placed on probation for 2 years. (F. D. C. No. 33794. Sample Nos. 22330–L, 41516–L, 56320–L.)

INFORMATION FILED: September 29, 1953, Eastern District of Pennsylvania, against Milton A. Calesnick, trading as Addison Laboratories, Philadelphia, Pa.

ALLEGED SHIPMENT: On or about April 30, June 30, and July 8, 1952, from the State of Pennsylvania into the States of New Jersey, Ohio, and Texas.

LABEL, IN PART: (Vials) "10 cc. Multiple-Dose Vial Testosterone Aqueous Macrosuspension Crystalline 100 mg./cc. Sterile—Intramuscular Distributed by Leon Rosengarten Dallas, Texas," "10 cc. Multiple-Dose Vial Lynntestro Aq Aqueous Macrosuspension Crystalline 100 mg./cc. Sterile—Intramuscular Distributed By Lynn Pharmacal Co. Camden, N. J.," and "10 cc. Multiple-Dose Vial List No. 1015 Estrone U. S. P. (2.0 mg. per cc.) * * * Mfg'd for The Caldwell & Bloor Co. Mansfield, Ohio."

NATURE OF CHARGE: *Testosterone* and *Lynntestro.* Adulteration, Section 501 (c), the purity and quality of the articles fell below that which they purported and were represented to possess. The articles were represented to be sterile, whereas they were not sterile but were contaminated with viable micro-organisms. Misbranding, Section 502 (a), the statement "Sterile" displayed upon the labels of the articles, was false and misleading.

Estrone. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since the article was represented to contain 2 milligrams of estrone per cubic centimeter, whereas the article in a number of the vials contained less than 2 milligrams of estrone per cublic centimeter; and, in a number of other vials, the article contained an excess of 2 milligrams of estrone per cubic centimeter. Misbranding, Section 502 (a), the label statements "Estrone U. S. P. (2.0 mg. per cc.) Each cc. contains a sterile aqueous macrosuspension of Estrone U. S. P. 2.0 mg." were false and misleading.

DISPOSITION: February 2, 1954. The defendant having entered a plea of guilty, the court fined him $300 and placed him on probation for 2 years.

4316. Adulteration of ammonium chloride tablets. U. S. v. 1 Drum * * *. (F. D. C. No. 36054. Sample No. 45675–L.)

LIBEL FILED: October 21, 1953, District of Massachusetts.

ALLEGED SHIPMENT: On or about March 24, 1953, by Nysco Laboratories, Inc. from Long Island City, N. Y.

PRODUCT: 1 drum containing 15,000 enteric coated *ammonium chloride tablets* at Wellesley, Mass.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ammonium Chloride Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and the quality of the article fell below the official standard. The standard specifies that a coating may be applied to ammonium chloride tablets, provided that such coating will disintegrate in the alimentary tract. The tablets of the article would not disintegrate in the alimentary tract.

DISPOSITION: January 19, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS *

4317. Misbranding of Magique Lotion. U. S. v. 11 Cases, etc. (F. D. C. No. 35629. Sample Nos. 59170–L, 59171–L.)

LIBEL FILED: September 14, 1953, Southern District of Florida.

ALLEGED SHIPMENT: On or about July 9 and 18, 1953, by the Lovely Lady Products Co., from El Monte, Calif.

PRODUCT: *Magique Lotion.* 11 cases, each containing 24 cartons and each carton containing a circular entitled "The Magique Lotion Story" and 1 bottle of *Magique Lotion,* at Miami, Fla., together with a number of cards reading, in part, "Here is Another Little Hint on Magique Lotion."

*See also Nos. 4301, 4313, 4315.

RESULTS OF INVESTIGATION: The product originally was labeled as "Slender Lotion" when shipped to the consignee by the Lovely Lady Products Co. With the July 18, 1953, shipment, the Lovely Lady Products Co. provided the consignee with new labeling designating the product as "Magique Lotion," which labeling consisted of a number of empty cartons and a number of loose labels. The consignee relabeled the product by affixing to each bottle one of the loose labels and packing into each of the empty cartons one of the relabeled bottles and one of the above-mentioned circulars.

LABEL, IN PART: (Carton) "Lovely Lady Formula 53 Magique Lotion Formerly Known as 'Slender Lotion'"; (bottle) "Lovely Lady Magique Lotion An Aid To Beauty * * * Contains Aluminum Potassium Sulphate, Magnesium Sulphate, Sodium-Hypochlorite (5%), Gum Camphor, Oil of Peppermint, Oil of Cloves, Benzoic Acid, Eugenol, Oil of Eucalyptus * * * Contents 16 Oz."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, the carton label and the aforesaid circulars and cards accompanying the article, were false and misleading. The statements represented and suggested that the article was an effective aid in reducing overweight; removing unwanted flesh; producing a slender, petite figure; benefiting the conditions of "flabby skin around our tummies," and "heavy hips and thighs, and legs"; removing fat from the body; eliminating "double chin"; and strengthening sagging chin muscles and sagging flabby flesh or skin. The article was not an effective aid for such purposes. The article was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: January 28, 1954. Default decree of forfeiture and destruction.

4318. Misbranding of kelp tablets. U. S. v. 18,000 Tablets, etc. (F. D. C. No. 35249. Sample Nos. 65645–L, 65646–L.)

LIBEL FILED: May 18, 1953, Northern District of Illinois.

ALLEGED SHIPMENT: On or about February 11, 1953, from Gardena, Calif.

PRODUCT: *Kelp tablets.* 18,000 tablets in bulk and 141 bottles, each bottle containing 125 tablets, at Chicago, Ill., in possession of Frederick Herrschner, together with a number of booklets entitled "Price List of Vi Vi Bx."

RESULTS OF INVESTIGATION: The shipment of the *kelp tablets* from California was a bulk shipment. After receipt of the tablets at Chicago, Ill., a number of the tablets were repackaged into bottles by the consignee. The above-mentioned booklets were printed for the consignee in January 1953.

LABEL, IN PART: (Bottle) "Vi Vi Bx * * * Pure Sea Kelp (dehydrated) * * * A Supplementary Source of Food Iodine 125 Tablets 10 grains each Frederick Herrschner Sole Distributors 410 So. Wells St., Chicago 7, Ill. One tablet furnishes 7 times the minimum daily requirement for iodine."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for excessive fatigue with aching muscles and cramps, overweight, drowsiness during the day, undue cold hands and feet, low metabolism, falling hair, and jittery nerves. The article was not an adequate and effective treatment for such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 14, 1954. Default decree of condemnation and destruction.

4319. Misbranding of Master violet ray devices. U. S. v. Master Appliances, Inc. Plea of guilty. Fine of $2,000, plus costs. (F. D. C. No. 35561. Sample Nos. 50206–L, 50207–L.)

INFORMATION FILED: October 20, 1953, Northern District of Indiana, against Master Appliances, Inc., Marion, Ind.

ALLEGED SHIPMENT: On or about October 10, 1951, and April 2, 1952, from the State of Indiana into the State of New York, of a number of devices known as *Master Violet Ray Outfit No. 2B* and *Master Violet Ray Outfit No. 9*.

PRODUCT: The *Master Violet Ray Outfit No. 2B* consisted of an electrical device and 3 glass tubes designated "No. 1 General Electrode," "No. 3 Comb-Rake Electrode," and "No. 12a Glass Electrode." The device itself consisted of a spark gap oscillator in a black bakelite-like plastic case having a green control knob on one end of the case and a hole at the other end. The control knob varied the size of the spark gap. Any one of the three electrodes could be fitted into the hole at the end of the case. The electrodes consisted of hollow glass tubes filled with gas and having metal sleeves on the ends which would fit into the oscillator.

The *Master Violet Ray Outfit No. 9* contained an electrical device and 1 glass tube designated "No. 1 General Electrode." The device was constructed similarly to the *Master Violet Ray Outfit No. 2B*, but was limited to accommodate only the "general electrode."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a leaflet entitled "Master Appliances for Health and Beauty," accompanying the devices, were false and misleading. The statements represented and suggested that the devices would provide an adequate and effective treatment for achieving good health, for relieving all pain and congestion, for stimulating the circulation, for restoring vigor and youth, for facial blemishes, for baldness, for preventing baldness, and for innumerable disorders, and that the devices would insure a clear, healthy complexion. The devices would not provide an adequate and effective treatment for such purposes and conditions, and they would not insure a clear, healthy complexion.

DISPOSITION: January 29, 1954. The defendant having entered a plea of guilty, the court fined it $2,000, plus costs.

4320. Misbranding of Tox Eliminator devices. U. S. v. 2 Devices, etc. (F. D. C. No. 36165. Sample No. 69842-L.)

LIBEL FILED: December 1, 1953, District of Utah.

ALLEGED SHIPMENT: Sometime in 1943 from Los Angeles, Calif.

PRODUCT: 2 *Tox Eliminator devices* at Ogden, Utah, in possession of N. Oscar Malan, together with a number of leaflets bearing the words "Tox Eliminator What it is." The *Tox Eliminator device* was an apparatus for flushing the colon.

RESULTS OF INVESTIGATION: The above-mentioned leaflets were printed locally for N. Oscar Malan, doing business as the Malan Clinic at Ogden, Utah. A number of leaflets were kept on a table in the waiting room of the Malan Clinic for distribution to customers.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the device were false and misleading. The statements represented and suggested that the device would provide an adequate and effective treatment for arthritis, rheumatism, neuritis, high blood pressure, low blood pressure, toxic heart conditions, stomach ulcers, intestinal ulcers, colitis, chronic appendicitis, gallbladder trouble, liver trouble, kidney trouble, bladder trouble, asthma, migraine, lumbago, stubborn skin diseases, and impure blood. The device would not provide an adequate and effective treatment for such conditions. The device was alleged to be misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 30, 1954. Default decree of condemnation. The court ordered that the devices and the leaflets be delivered to the Food and Drug Administration.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS 4301 TO 4320

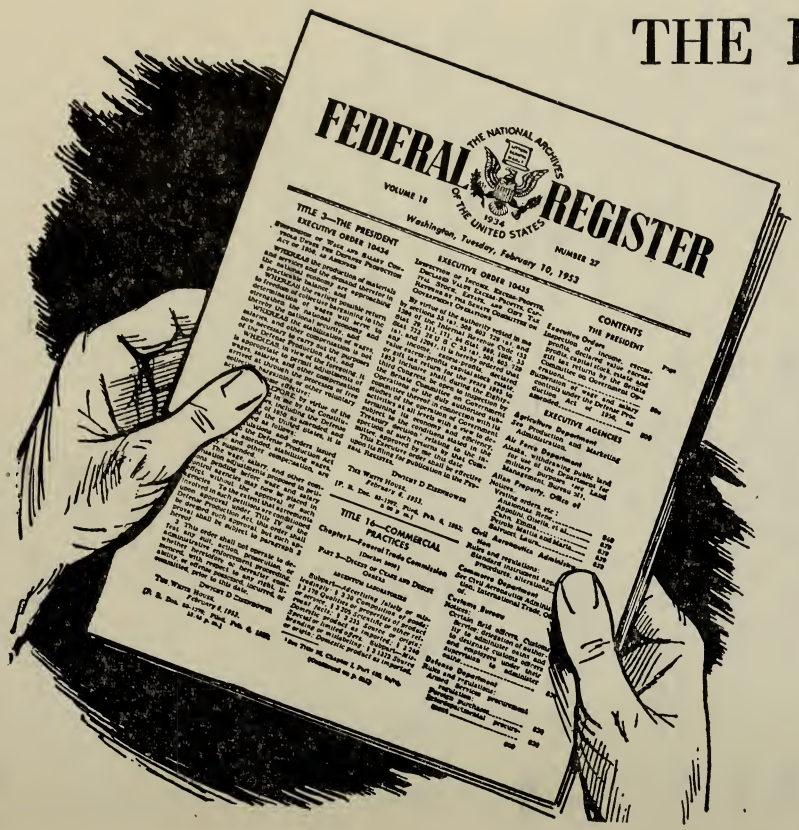
PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4302, 4310) Prosecution contested.

[1] (4302, 4310) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1955



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D. D. N. J., F. D. C. 4321–4340 Issued March 1955

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4321–4340

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 8, 1955.*

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 4328, 4336.

331433—55——1

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4321. Misbranding of dextro-amphetamine sulfate tablets, pentobarbital sodium capsules, Seconal Sodium capsules, thyroid tablets, sulfisoxazole tablets, and methyltestosterone tablets. U. S. v. Reed's Cut Rate Drugs, Inc., Saul M. Blumenthal, Robert P. Alexander, Frank R. Cooley, Robert N. Dodd, and Jack M. Gavant. Pleas of not guilty by corporation and Defendants Blumenthal and Cooley; pleas of nolo contendere by Defendants Alexander, Dodd, and Gavant. Tried to the court and jury. Verdict of guilty against corporation; verdicts of not guilty against Defendants Blumenthal and Cooley. Fine of $500 against corporation, $150 against Defendant Alexander, $50 against Defendant Dodd, and $200 against Defendant Gavant. Corporation placed on probation for 1 year and Defendants Alexander, Dodd, and Gavant placed on probation for 2 years. (F. D. C. No. 35160. Sample Nos. 2490–L, 59311–L, 59313–L, 59316–L, 59317–L, 59634–L to 59638–L, incl.)

INFORMATION FILED: September 3, 1953, Northern District of Georgia, against Reed's Cut Rate Drugs, Inc., Atlanta, Ga., Saul M. Blumenthal, president and general manager of the corporation, Frank R. Cooley and Jack M. Gavant, store managers and pharmacists for the corporation, Robert P. Alexander, a pharmacist, and Robert N. Dodd, a clerk employed by the corporation.

NATURE OF CHARGE: On or about December 22, 1952, and March 3, 4, 5, 6, 9, 10, and 12, 1953, while a number of *dextro-amphetamine sulfate tablets*, *pentobarbital sodium capsules*, *Seconal Sodium capsules*, *thyroid tablets*, *sulfisoxazole tablets* and *methyltestosterone tablets* were being held for sale at Reed's Cut Rate Drugs, Inc., after shipment in interstate commerce, various quantities of *dextro-amphetamine sulfate tablets*, *thyroid tablets*, *sulfisoxazole tablets*, and *methyltestosterone tablets* were dispensed without a prescription from a practitioner licensed by law to administer such drugs, and various quantities of *pentobarbital sodium capsules* and *Seconal Sodium capsules* were dispensed upon requests for refills of written prescriptions for such drugs without obtaining authorization by the prescribers. The corporation and Saul M. Blumenthal were charged with causing the act of dispensing involved in each of the 10 counts of the information, and Jack M. Gavant in counts 1, 2, 3, and 4, Robert P. Alexander in counts 5, 6, and 7, Frank R. Cooley in count 8, and Robert N. Dodd in counts 9 and 10 were joined as defendants. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: The corporation and Defendants Blumenthal and Cooley entered pleas of not guilty, and Defendants Alexander, Dodd, and Gavant entered pleas of nolo contendere. The case came on for trial before the court and jury on March 29, 1954, and at the conclusion of the trial on March 30, 1954, the jury returned a verdict of guilty with respect to the corporation and verdicts of not guilty with respect to Defendants Blumenthal and Cooley. On April 12, 1954, the court fined the corporation $500, Defendant Alexander $150, Defendant Dodd $50, and Defendant Gavant $200. The court also placed the corporation on probation for 1 year and Defendants Alexander, Dodd, and Gavant on probation for 2 years.

4322. Misbranding of pentobarital sodium capsules and dextro-amphetamine sulfate tablets. U. S. v. J. A. Miller (Mar-Main Pharmacy), Glenn L. Handshaw, Ralph Woolley, and Joseph A. Bills. Pleas of nolo contendere. Fine of $300 against J. A. Miller and $100 against each of the other defendants, plus costs. (F. D. C. No. 35124. Sample Nos. 9700–L to 9703–L, incl., 10070–L, 10073–L, 10075–L, 10078–L.)

INFORMATION FILED: September 9, 1953, Northern District of Indiana, against J. A. Miller, trading as Mar-Main Pharmacy, South Bend, Ind., and Glenn L. Handshaw, Ralph Woolley, and Joseph A. Bills, pharmacists.

NATURE OF CHARGE: On or about September 9, 13, and 26, November 13, 18, and 25, and December 3, 1952, while a number of *pentobarbital sodium capsules* and *dextro-amphetamine sulfate tablets* were being held for sale at the Mar-Main Pharmacy, after shipment in interstate commerce, various quantities of such drugs were dispensed upon requests for refills of written prescriptions therefor without obtaining authorization by the prescribers. J. A. Miller was charged with causing the acts of dispensing involved in each of the 8 counts of the information; Glenn L. Handshaw was joined as a defendant in 3 counts; Ralph Woolley, in 2 counts; and Joseph A. Bills, in 2 other counts of the information. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: April 29, 1954. The defendants having entered pleas of nolo contendere, the court fined J. A. Miller $300 and each of the other defendants $100, plus costs.

4323. Misbranding of dextro-amphetamine sulfate tablets, sulfathiazole tablets, and amphetamine sulfate tablets. U. S. v. Norbert A. Spalding (Spalding Drug Co.), Guy E. Taliaferro, and Marvin M. Gray. Pleas of guilty. Fine of $150, plus costs, against each individual. (F. D. C. No. 34830. Sample Nos. 46552–L, 46561–L to 46564–L, incl.)

INFORMATION FILED: May 13, 1953, Northern District of Alabama, against Norbert A. Spalding, trading as the Spalding Drug Co., Sheffield, Ala., and Guy E. Taliaferro, a pharmacist, and Marvin M. Gray, a clerk in the business.

NATURE OF CHARGE: On or about July 30 and August 12, 13, and 15, 1952, while a number of *dextro-amphetamine sulfate tablets*, *sulfathiazole tablets*, and *amphetamine sulfate tablets* were being held for sale at the Spalding Drug Co., after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Defendant Spalding was charged with causing the acts of dispensing involved in each of the counts of the information; Defendant Taliaferro was joined as a defendant in counts 2 and 4; and Defendant Gray was joined as a defendant in count 5 of the information. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: April 2, 1954. The defendants having entered pleas of guilty, the court fined each defendant $150, plus costs.

4324. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Gonzales B. Azcona (Hi-Way Drug Store), and Louis A. Bourg. Plea of not guilty by Gonzales B. Azcona and plea of nolo contendere by Louis A. Bourg. Fine of $25 on each of counts 1 and 2 against Louis A. Bourg, with imposition of sentence suspended on count 3 and this defendant placed on probation for 1 year. Gonzales B. Azcona tried to the court and found not guilty. (F. D. C. No. 34842. Sample Nos. 46975–L, 46976–L, 46978–L.)

INFORMATION FILED: June 2, 1953, Eastern District of Louisiana, against Gonzales B. Azcona, trading as the Hi-Way Drug Store, New Orleans, La., and Louis A. Bourg, a pharmacist in the store.

NATURE OF CHARGE: On or about September 23 and 29 and October 2, 1952, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at the Hi-Way Drug Store, after shipment in interstate commerce, the defendants were alleged to have caused various quantities of the drug to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: Gonzales B. Azcona entered a plea of not guilty and Louis A. Bourg entered a plea of nolo contendere. On June 24, 1953, the court fined Louis A. Bourg $25 on each of counts 1 and 2 of the information, suspended the imposition of sentence on count 3, and placed this defendant on probation for 1 year. The case against Gonzales B. Azcona came on for trial before the court without a jury on July 1, 1954. The trial was concluded on the same day, with the return of a verdict of not guilty for this defendant.

4325. Misbranding of pentobarbital sodium capsules. U. S. v. Fannie Smith, also known as Fannie Smith Shell. Plea of not guilty. Tried to the court and jury. Plea changed to guilty after introduction of Government's evidence. Sentence of 1 year in jail. (F. D. C. No. 34335. Sample Nos. 12124–L, 12125–L, 35698–L.)

INFORMATION FILED: On or about April 14, 1953, Eastern District of Tennessee, against Fannie Smith, also known as Fannie Smith Shell, Johnson City, Tenn.

NATURE OF CHARGE: On or about June 11 and July 16, 1952, while a number of *pentobarbital sodium capsules* were being held for sale at Johnson City, Tenn., after shipment in interstate commerce, the defendant caused a number of the capsules to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: The defendant having entered a plea of not guilty, the case came on for trial before the court and jury on March 8, 1954. After the introduction of the Government's evidence, the defendant entered a plea of guilty, and on March 29, 1954, the court sentenced the defendant to serve 1 year in jail.

4326. Misbranding of sulfathiazole tablets and sulfadiazine tablets. U. S. v. Standard Drug Co. and Ottice H. Blankenship. Pleas of guilty. Fine of $200 against company and $150 against individual. (F. D. C. No. 34829. Sample Nos. 46553–L to 46555–L, incl.)

INFORMATION FILED: May 13, 1953, Northern District of Alabama, against the Standard Drug Co., a partnership, Sheffield, Ala., and Ottice H. Blankenship, a partner in the partnership.

NATURE OF CHARGE: On or about July 30 and August 12 and 15, 1952, while a number of *sulfathiazole tablets* and *sulfadiazine tablets* were being held for sale at the Standard Drug Co., after shipment in interstate commerce, the defendants caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: April 2, 1954. The defendants having entered pleas of guilty, the court fined the partnership $200 and the individual $150.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4327. Misbranding of Tryptacin tablets. U. S. v. 38 Dozen Bottles * * *. Tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 33948. Sample No. 19876–L.)

LIBEL FILED: October 20, 1952, District of Minnesota.

ALLEGED SHIPMENT: On or about October 8, 1952, by Rhodes Pharmacal Co., Inc., from Cleveland, Ohio.

PRODUCT: 38 dozen bottles of *Tryptacin tablets* at St. Paul, Minn.

RESULTS OF INVESTIGATION: An advertisement in a Minneapolis Sunday newspaper for September 28, 1952, announced the availability of "New Tryptacin An Achievement of Science" at various drug stores in the area. The advertisement consisted of a full page ad reading, in part, as follows: "We have proved it! In actual clinical X-ray tests patients showed almost complete healing in 4 weeks * * * New Tryptacin relieves Acid Pain of Diagnosed Stomach Ulcers, Acid Indigestion, Gas, After-Eating Distress * * * X-Rays revealed that a number of ulcer patients tested showed almost complete healing in 4 weeks."

LABEL, IN PART: (Bottle) "Tryptacin Rhodes For the Temporary Relief of Excess Gastric Acidity 100 Tablets Sole Distributors Rhodes Pharmacal Co., Inc., Cleveland, Ohio * * * Each tablet contains Aluminum Hydroxide Gel (Dried), Magnesium Trisilicate, Magnesium Oxide, Polyamine Methylene Resin, Ethyl p-Aminobenzoate (Benzocain) and water soluble Chlorophyllins in a special demulcent base."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in that its label failed to state the conditions or diseases for which the article was intended to be taken, and its label failed also to bear adequate directions for use in the treatment of such conditions and diseases.

DISPOSITION: Rhodes Pharmacal Co., Inc., appeared as claimant and filed an answer on October 30, 1952, denying that the product was misbranded. Thereafter, the Government filed a motion for summary judgment on the grounds that since the newspaper advertisement on its face recommended and sug-

gested the product for the treatment of stomach ulcers and since the labeling did not specify stomach ulcers as one of the conditions or diseases for which the product was offered, there was no fact in dispute and the product was therefore misbranded. The court denied this motion when the claimant submitted affidavits tending to raise a question of fact as to the meaning of the advertisement. Thereafter, a set of written interrogatories and a set of requests for admissions were served upon the claimant. The claimant filed answers to the requests for admissions and to certain of the interrogatories, accompanied by objections to the remainder of the interrogatories.

On May 25, 1953, the court sustained some of the objections and overruled the others. Answers to the interrogatories on which objections had been overruled were filed subsequently, and on June 17, 1953, the case came on for trial before the court without a jury. At the conclusion of the trial, the matter was taken under advisement by the court; and, on September 4, 1953, the court handed down the following opinion:

BELL, *District Judge:* "This is a seizure action brought under Section 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 334 (a). It was begun by the filing of a libel of information charging that the seized article was a drug which had been shipped in interstate commerce by the Rhodes Pharmacal Company of Cleveland, Ohio, and that the article was misbranded while in interstate commerce under 21 U. S. C. 352 [502] (f) (1) by reason of the failure of its labeling to bear adequate directions for use. The charges arise out of the following facts.

"A full page advertisement for 'Tryptacin' appeared in the St. Paul Pioneer Press at approximately the same time that the drug was offered for sale in that city. The advertisement makes prominent reference to stomach ulcers as well as other conditions, while the label on the bottle of 'Tryptacin' bears no reference whatever to stomach ulcers. Libelant alleges that the advertisement recommends and suggests the drug for treatment of stomach ulcers and that the failure of the labeling of the drug to state that it is to be used in treating 'stomach ulcers,' causes the directions for use in the labeling to be inadequate and the product to be misbranded under 21 U. S. C. 352 [502] (f) (1). Libelant further charges that the directions for use which appear on the labeling do not, regardless of whether the words 'stomach ulcers' appear in the labeling, constitute adequate directions for use in the treatment of that disease. Claimant's position is that the advertisement represents only that 'Tryptacin' is intended for use as an antacid and that the directions for use on the label are adequate for that usage. There is no issue as to the composition of 'Tryptacin' or its effect on the human body.

"The first question raised deals with the meaning to be given to the language of the advertisement. It is clear to me that the full page advertisement offers 'Tryptacin' to the public as something more than an antacid or a palliative for acid pain. In the upper left hand corner of the advertisement there are described clinical tests in which ulcer patients 'Showed Almost Complete Healing' after treatment with 'Tryptacin.' This language, in my opinion, can have been put into the advertisement for no other purpose than to cause the sufferer from stomach ulcers to believe that the drug would give more than relief from pain of stomach ulcers, and that it will, in fact, provide a cure. Nor does the language of the advertisement dealing with the power of 'Tryptacin' to neutralize stomach acidity overcome the impression conveyed by the portion of the advertisement referred to above.

"The contention of claimant that the drug is sold only to give symptomatic relief from acid pain requires the portion of the advertisement relating to the 'healing' of stomach ulcers to be disregarded and that the Court ignore the obvious import of the advertisement as a whole. This would manifestly place an unreasonable interpretation on the advertisement. 'The ultimate impression upon the mind of the reader arises from the sum total of not only what is said but also of all that is reasonably implied.' *Aronberg* v. *Federal Trade Commission*, 132 F. 2d 165, 167 (C. A. 7). I can see no reason for placing any language at all dealing with the healing of stomach ulcers

in the advertisement if 'Tryptacin' is offered only as a palliative for the relief of acid pain. See: *Bradley* v. *United States*, 264 Fed. 79 (C. A. 5); *United States* v. *46 Cartons * * * 'Fairfax Cigarettes,'* (D. N. J., 1953). Unreported, but summarized in 21 LW 2606, June 16, 1953. If it is to be used as a simple antacid, the full page ad is entirely out of place. Certainly the reader of the advertisement would not gather from it the idea that 'Tryptacin' is for temporary palliative relief alone, whether he is one of 'the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze,' *United States* v. *62 Packages * * * 'Marmola Prescription Tablets,'* 48 F. Supp. 878, 887 (W. D. Wis.); or 'the ordinary person who is neither savant nor dolt, who lacks special competency with reference to the matter at hand but has and exercises a normal measure of the layman's common sense and judgment,' *United States* v. *88 Cases * * * 'Bireley's Beverage,'* 187 F. 2d 967, 971 (C. A. 3).

"In addition to reading and examining the advertisement, I base my finding as to the impression conveyed by the advertisement upon the evidence presented on that point. Libelant's witnesses, Dr. James N. Mosel and Dr. Howard P. Longstaff, experts in the field of advertising and marketing psychology, presented exhaustive analyses of the content of the advertisement and the effect which it was intended to have upon the prospective purchaser of the drug. Such testimony is admissible to determine the meaning of an advertisement. *Federal Trade Commission* v. *National Health Aids, Inc.*, 108 F. Supp. 340 (D. Md.).

"Moreover, Dr. Mosel introduced evidence relative to two hundred individuals whom he surveyed concerning the impression which they received from the 'Tryptacin' advertisement. A substantial portion of those interviewed indicated that they received the impression from the advertisement that 'Tryptacin' would 'stop,' 'cure' or otherwise bring about some permanent relief of ulcers. The forms filled out by the individuals questioned, interview cards, and tabulations made by Dr. Mosel of the answers received, were placed in evidence by Libelant.

"Other evidence of libelant which I considered in reaching my opinion as to the meaning of the advertisement included testimony of two persons who purchased 'Tryptacin' in the belief that the advertisement offered a cure for stomach ulcers, and the testimony of libelant's witness, Dr. Moses Barron, a specialist in internal medicine, who has treated many cases of stomach ulcers. Dr. Barron testified that in his opinion the ulcer patient would receive from the 'Tryptacin' advertisement the impression that the drug was offered as a cure for stomach ulcers. An expert medical witness is qualified to express such an opinion. *Charles of the Ritz Distributors Corporation* v. *Federal Trade Commission*, 143 F. 2d 676 (C. A. 2).

"Claimant's evidence on the import of the language of the advertisement consisted of the testimony of two representatives of a firm which handles 'Tryptacin' advertising and testimony of a number of physicians. The two advertising men testified (one on deposition) that in their opinion the advertisement offered 'Tryptacin' as a means of relieving acid pain and not of curing stomach ulcers. They also testified that they had showed the advertisement to a number of their associates in the advertising business, to newspaper censorship boards and to other persons, and inquired as to the impression which the advertisement conveyed. Both witnesses testified that not a single person questioned received the impression that the advertisement offered a cure for stomach ulcers. The doctors who testified for claimant stated that they had discussed the meaning of the advertisement with doctors, nurses, patients and other persons, and again that no person received from the advertisement the impression that the product would cure stomach ulcers. In no case did the witnesses offer any written evidence concerning such interviews, and it does not appear that such discussions were systematically conducted. The likelihood of error or prejudice developing in the course of such interviews would seem to be great, particularly since none of the witnesses of claimant, including both advertising men and doctors, were qualified by education or experience in the taking of formal public opinion surveys.

"The second question which I have found it necessary to answer is, having established that the advertisement offers a cure for stomach ulcers, are the directions for use adequate in the treatment of that disease. Libelant urges

that the labeling directions are not adequate simply by failure of the labeling to include a statement that the drug is to be used for 'stomach ulcers.'[1] That such a requirement is a requisite of adequate directions for use is borne out by the decisions. The principle was well stated in *United States* v. *Various Quantities* * * * *'Instant Alberty Food,'* 83 F. Supp. 882, 885 (D. C. D. C.):

> The words "adequate directions for use" necessarily relate to some purpose which is to be served by the use, and that purpose must be consistent with the intent of the Act as a whole to protect the public health. For what purpose are drugs used? Obviously, as a remedy for some ailment of the body. It seems equally obvious that no drug can be said to contain in its labeling adequate directions for its use, unless every ailment of the body for which it is, through any means, held out to the public as an efficacious remedy be listed in the labeling, together with instructions to the user concerning the quantity and frequency of dosage recommended for each particular ailment.

See also: *Alberty Food Products, a partnership, et al* v. *United States*, 194 F. 2d 463 (C. A. 9); *Colgrove* v. *United States* 176 F. 2d 614 (C. A. 9).

"Libelant also charges that the directions for use on the label of 'Tryptacin' are not adequate because, even if they were followed, a cure from stomach ulcers would not result. On this point, Libelant's witness, Dr. Barron, who possesses impressive qualifications, including the fact that he has diagnosed and treated numerous cases of stomach ulcers in the course of his practice, testified that the directions for use as they appear on the bottle label of 'Tryptacin' are not adequate. Dr. Barron gave as reasons for this statement the fact that every case of stomach ulcers must be treated as an individual problem; that other drugs as well as antacids are sometimes used in the treatment of stomach ulcers and that different antacids are used in different types of cases; that factors other than the administration of drugs are involved in the healing of an ulcer; that untreated or improperly treated stomach ulcers may become cancerous and unresponsive to surgery; and that stomach ulcers is a disease which should not be treated except under the supervision of a physician. Dr. Hugh A. McGuigan, who testified for claimant and who also possessed extensive qualifications in the fields of pharmacology and therapeutics, stated that in his opinion the directions for use on the label of 'Tryptacin' give to the user of the product sufficient directions to enable intelligent and safe self-treatment. Dr. McGuigan testified on cross-examination, however, that diet and rest, in addition to administration of an antacid, and other drugs, are sometimes factors in the treatment of stomach ulcers. In this last statement, Dr. McGuigan agreed in effect with Dr. Barron. It is apparent to me that the directions for use are not complete and consequently are inadequate.

"Findings of Fact, Conclusions of Law and an Order for Judgment will be entered accordingly."

In accordance with the above opinion, the court made its findings of fact and conclusions of law; and, on September 15, 1953, the court entered a decree of condemnation and destruction.

4328. Adulteration and misbranding of laxative quinine tablets. U. S. v. 75 Packages * * *. (F. D. C. No. 36214. Sample No. 56166–L.)

LIBEL FILED: December 29, 1953, Northern District of New York.

ALLEGED SHIPMENT: On or about September 2, 1952, from Worcester, Mass.

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[1] The Secretary of Health, Education, and Welfare, acting under Section 701 (a) of the Act, 21 U. S. C. 371 (a), has promulgated the following interpretative regulations of Section 502 (f) (1) of the Act; 21 U. S. C. 352 (f) (1):

21 C. F. R. 1,106 *Drugs and Devices: Directions for use.*—(a) *Adequate Directions for use.* "Adequate directions for use" means directions under which the layman can use a drug . . . safely and for the purpose for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug . . . is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug . . . is commonly used; . . .

PRODUCT: 75 packages of *laxative quinine tablets* at Utica, N. Y., in possession of Bockman's Drug Store, Inc. Analysis showed that the article consisted of red compressed tablets containing quinine, cinchonine sulfate, aloin, gamboge, phenolphthalein, capsicum, and 0.59 grain of acetanilid.

RESULTS OF INVESTIGATION: The tablets were shipped in interstate commerce in bulk containers, and upon receipt by the consignee, they were repackaged and relabled.

LABEL, IN PART: (Bulk container) "10,000 Tablets * * * Pink Each tablet contains: Acetanilid (⅝ gr.) 40 mg., Quinine Phosphate, Cinchonine Sulfate, Aloin, Gamboge, Phenolphthalein and Capsicum * * * Caution: * * * Frequent or continued use may cause a dependence upon laxatives"; (package) "Recommended For Colds, Coughs, La Grippe, Malarial Headaches and Neuralgia Bocan's Laxative-Quinine Compound Useful in the Treatment of * * * Chills * * * Fever Each Tablet contains ½ gr. Acetanilid * * * Contents 20 Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article in the packages differed from that which it purported to possess since the article contained more than ½ grain of acetanilid.

Misbranding, Section 502 (a), certain statements on the package label and in a leaflet enclosed with each package were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for colds, coughs, bronchial troubles, la grippe, catarrh, neuralgia, malarial troubles, malarial headaches, chills, and fever. The article was not an adequate and effective treatment for such purposes. Further misbranding, Section 502 (e) (2), the package label failed to bear the common or usual name of each active ingredient since aloin, gamboge, and phenolphthalein were not declared; and, Section 502 (f) (2), the labeling of the article in the packages failed to bear a warning that the article should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, or a warning that frequent or continued use may result in a dependence on laxatives.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: February 6, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4329. Adulteration of alpha-tocopherol and alpha-tocopheryl acetate. U. S. v. Pharmaceutical Co. of New Jersey and Theodore R. Kupchik. Pleas of guilty. Fine of $3 against company and $1,500 against individual. (F. D. C. No. 33779. Sample Nos. 22855-L, 22859-L, 22860-L.)

INFORMATION FILED: April 13, 1953, District of New Jersey, against the Pharmaceutical Co. of New Jersey, a corporation, Bloomfield, N. J., and Theodore R. Kupchik, president of the corporation.

ALLEGED SHIPMENT: On or about June 7 and 18, 1951, from the State of New Jersey into the State of New York.

LABEL, IN PART: (Bottle) "Darrylle Chemical Co. 121 Broad St., New York 4, N. Y. 500 Grams Alpha Tocopheryl Acetate (Vitamin E Acetate)"; (ampul)

*See also No. 4328.

"Alpha Tocopherol Nepera (Vitamin E) U. S. P. Nepera Chemical Co. Inc. Yonkers, N. Y. Manufacturing Chemists"; (bottle) "Alpha Tocopherol Nepera (Vitamin E) U. S. P. Acetate Nepera Chemical Co. Inc., Yonkers, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of a portion of the *alpha-tocopheryl acetate* differed from that which it purported and was represented to posses in that it purported and was represented to contain 99.4 percent alpha-tocopheryl acetate, whereas it contained less than that amount.

Further adulteration, Section 501 (d) (2), a product containing less than 95 percent of alpha-tocopherol had been substituted for a product containing not less than 95 percent of alpha-tocopherol, which the article designated as "Alpha Tocopherol Nepera" purported and was represented to be; and a product containing little or no alpha-tocopheryl acetate had been substituted for a portion of the article which purported to be and was represented as *alpha-tocopheryl acetate.*

DISPOSITION: March 5, 1954. The defendants having entered pleas of guilty, the court fined the corporation $3 and the individual $1,500.

4330. Adulteration of halazone tablets. U. S. v. 67 Cases * * *. (F. D. C. No. 36171. Sample No. 52637–L.)

LIBEL FILED: December 11, 1953, Eastern District of New York.

ALLEGED SHIPMENT: On or about November 28, 1951, by the City Chemical Corp., from Fort Lawton, Wash., to Jersey City, N. J., and from there transported to Brooklyn, N. Y., on or about September 9, 1953.

PRODUCT: 67 cases, each containing 300 bottles, of *halazone tablets* at Brooklyn, N. Y.

LABEL, IN PART: (Bottle) "100 Tablets (or 100 Water Purification Tablets) * * * Halazone N. N. R. Abbott * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium carbonate, sodium chloride and boric acid."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since the article contained less than 90 percent of the labeled amount of halazone, the minimum permitted by the standard.

DISPOSITION: March 3, 1954. Default decree of condemnation and destruction.

4331. Adulteration and misbranding of adhesive bandages. U. S. v. American White Cross Laboratories, Inc., and Irving Tow. Pleas of guilty. Fine of $1,600 against corporation and $1,600 against individual. (F. D. C. No. 33770. Sample Nos. 37766–L, 37800–L, 37801–L, 37808–L.)

INFORMATION FILED: May 6, 1953, Southern District of New York, against American White Cross Laboratories, Inc., New Rochelle, N. Y., and Irving Tow, general manager of the corporation.

ALLEGED SHIPMENT: On or about December 5, 1951, January 24, and April 21, 1952, from the State of New York into the State of New Jersey.

LABEL, IN PART: (Box) "White Cross Sterile Waterproof 10 Adhesive Bandages * * * Plain Pad [or "Mercurochrome Pad"]."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive Absorbent Bandage," a drug the name of

which is recognized in the United States Pharmacopeia, an official compendium, and the quality and purity of the article fell below the official standard since the article was not sterile but was contaminated with viable micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterile" was false and misleading.

DISPOSITION: February 25, 1954. The defendants having entered pleas of guilty, the court fined the corporation $1,600 and the individual $1,600.

4332. Adulteration and misbranding of rubber prophylactics. U. S. v. 4,995 Gross * * *. (F. D. C. No. 33352. Sample Nos. 37686–L, 37687–L.)

LIBEL FILED: On or about July 25, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about February 29 and March 18 and 25, 1952, by the Allied Latex Corp., from East Newark, N. J.

PRODUCT: 4,995 gross of *rubber prophylactics* at New York, N. Y. Examination of 288 prophylactics showed that 4.8 percent were defective in that they contained holes.

LABEL, IN PART: (Carton) "Stags Prophylactics One Gross."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label designation "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: April 23, 1954. Goodwear Rubber Co., Inc., New York, N. Y., claimant, having filed an answer and later withdrawn its claim and answer, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4333. Misbranding of Sacrasol capsules. U. S. v. Edwin K. Osmun (Physicians' Ethical Products). Plea of not guilty. Tried to the court. Verdict of guilty. Fine of $1,000, plus costs. (F. D. C. No. 32752. Sample No. 75706–K.)

INFORMATION FILED: July 10, 1952, Northern District of Illinois, against Edwin K. Osmun, trading as Physicians' Ethical Products, Chicago, Ill.

ALLEGED SHIPMENT: On or about March 10, 1950, from the State of Illinois into the State of Iowa.

LABEL, IN PART: (Bottle) "Sacrasol Active Ingredients Syzygium Vesicaria Rhus. Aromatic Apis Virus Lithium Benzoate Phosphoric Acid (Dilute) Uranium Nitricum 1/1000 Gr. per Cap. Thiamin Hydrochloride."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on circulars entitled "Sacrasol in Diabetes Mellitus" and "Thiamin Chloride Essential For The Disposal of Starches and Sugars," on a card entitled "Announcement," and in a letter dated March 8, 1950, which circulars, card, and letter accompanied the article, were false and misleading. The statements represented and suggested and created the impression that the article was an adequate and effective treatment for diabetes, itching skin, excessive thirst, and abnormal appetite associated with diabetes; that the article was an adequate and effective treatment for preventing toxic build-up in the liver or kidneys;

*See also Nos. 4328, 4331, 4332.

for correcting dysfunctions in the carbohydrate metabolism; for disposing of excess sugar in the blood and urine; for diabetic ulcerations; for weakness, emaciation, enuresis due to atony, hematuria, and cystitis; and that the article was an adequate and effective treatment for all forms of urinary and kidney difficulties, nephralgia, dropsy, flatulence, diarrhea, periosteal inflammation, abscesses, gangrene, gout, and nettle rash. The article was not an adequate and effective treatment for the diseases and conditions stated and implied.

DISPOSITION: The defendant having entered a plea of not guilty, the case came on for trial before the court without a jury on March 22, 1954. The trial was concluded on the same day, with the return by the court of a verdict of guilty and the imposition of a fine of $1,000, plus costs, against the defendant.

4334. Misbranding of homeopathic drugs. U. S. v. 40 Bottles, etc. (F. D. C. No. 33320. Sample No. 33367–L.)

LIBEL FILED: July 7, 1952, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On various dates between November 17, 1950, and March 29, 1952, from Chicago, Ill.

PRODUCT: 40 1-ounce bottles, 116 2-ounce bottles, and 17 1-pound bottles of *calcarea flourica tablets*, 1 2½-pound box of *calcarea fluorica*, 28 1-ounce bottles and 15 1-pound bottles of *calcarea phosphate tablets*, 9 1-ounce bottles, 41 2-ounce bottles, and 10 1-pound bottles of *calcarea sulfate tablets*, 1 2-pound box and 2 1-pound bottles of *ferrum phosphate*, 21 1-pound bottles and 81 2-ounce bottles of *ferrum phosphate tablets*, 30 1-ounce bottles, 48 2-ounce bottles, and 9 1-pound bottles of *kali muriaticum tablets*, 17 1-ounce bottles and 37 2-ounce bottles of *kali phosphate tablets*, 5 1-ounce bottles, 21 2-ounce bottles, and 15 1-pound bottles of *kali sulfate*, 32 1-ounce bottles and 7 1-pound bottles of *magnesia phosphate tablets*, 127 2-ounce bottles and 2 1-pound bottles of *natrum muriaticum tablets*, 45 1-ounce bottles, 46 2-ounce bottles, and 6 1-pound bottles of *natrum phosphate tablets*, 40 1-ounce bottles, 91 2-ounce bottles, and 7 1-pound bottles of *natrum sulfate tablets*, 49 1-ounce bottles, 139 2-ounce bottles, and 16 1-pound bottles of *silicea tablets*, 41 1-pound bottles of various kinds of *special formula tablets*, and 2 1-pound bottles containing a mixture of *homeopathic drugs in powder form* at Milwaukee, Wis., in possession of Louis Pauly, together with a number of booklets entitled "My Open Letter No. 12," "Supplement Letter No. 15 November, 1949," "Supplement Letter No. 6 June, 1945," and "Supplement Letter No. 19 April, 1952"; a number of leaflets entitled "Letter No. 13," "Excerpts From My Coming Letter No. 14 for 1949," "I am calling this sheet my No. 17 Letter, July, 1951," and "Letter No. 18"; a number of leaflets headed "Louis Pauly"; and a number of blotters bearing the words "Professional Comments On The Bio-Chemic System of Medicine" and "My Proposed Cover Page For Letter No 16 November, 1950."

RESULTS OF INVESTIGATION: The above-mentioned booklets, leaflets, and blotters were printed in the Milwaukee, Wis., area for the consignee.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the articles, namely, the above-mentioned booklets, leaflets, and blotters accompanying the articles, contained statements which were false and misleading. Such labeling contained certain general statements which represented and suggested that the articles constituted adequate and effective cure, mitigation, treatment, and prevention of chronic diseases, lymphoblastoma, all skin diseases, tubercu-

losis, female organ tumors, Bright's disease, high blood pressure, psoriasis, eczema, jungle rot, ichthyosis, skin cancer, colitis, abscess, piles, shingles, sinus affections, rectal fistula, polio, every type of dermatitis and many other so-called chronic diseases, asthma, Buerger's disease, Hodgkin's disease, nervous and mental breakdown, gallbladder trouble, glandular affections, epilepsy, sciatica, diabetes, rheumatism, earache, all curable diseases, cerebral palsy, multiple sclerosis, Raynaud's disease, lupus erythema, pemphigus, affections of the tonsils, ulcers, bad heart condition, stroke, hemorrhages, poor memory, inability to concentrate or think clearly, gallstones, and newer cases of hemorrhoids, and to cause almost instant improvement in pneumonia and other fevers, acne, anemia, bronchitis, children's bed wetting, carbuncles, dyspepsia, impetigo, insomnia, neuritis, paralysis of legs, prostate gland affections, sties on eyelids, fistula, and menopause affections.

In addition, a booklet entitled "My Open Letter No. 12" contained specific statements which represented and suggested that the *ferrum phosphate*, *calcarea fluorica*, *kali muriaticum*, and *silicea* would cure all skin ailments, including psoriasis and jungle rot, would heal all cases of eczema of long standing, and would cure extreme cases of acne; that the *ferrum phosphate*, *calcarea fluorica*, and *silicea* would cure abscess of the rectum; that the *ferrum phosphate* and *kali muriaticum* would prevent bronchitis; that the *ferrum phosphate* and *silicea* would rid one of sinus trouble; that the *magnesia phosphate*, *ferrum phosphate*, and *kali muriaticum* would cure infantile paralysis; and that the *silicea*, *magnesia phosphate*, *calcarea phosphate*, and *natrum phosphate* would be helpful in multiple sclerosis and paralysis.

The leaflets entitled "Letter No. 13" and the booklets entitled "Supplement Letter No. 15" contained specific statements which represented and suggested that the *magnesia phosphate*, *kali phosphate*, and *kali muriaticum* would cure polio; that the *ferrum phosphate* would prevent polio; that the *natrum muriaticum* would relieve conditions causing dropsy; and that the *calcarea fluorica 6x* would relieve high blood pressure and bring back lost elasticity of the circulatory system.

The booklets entitled "Supplement Letter No. 15" contained specific statements which represented and suggested that the *special formula tablets* labeled, in part, "Homeopathic Compound Tablets—60% Silicea 6x" or "Special Formula Tablets * * * Each tablet contains Silicea 6x," would cure piles; that the *special formula tablets* labeled, in part, "Each Tablet Contains Silicea 6x * * * Ferr. Phos 6x * * * Kali Sulf 6x," would cure 95 percent or more of sinus sufferers; that the *kali phosphate* and *magnesia phosphate 3x* constituted remedies for asthma; and that the *calcarea fluorica 12x*, *ferrum phosphate 12x*, and *silicea 12x* would cure all skin diseases.

The leaflets entitled "I am calling this sheet my No. 17 Letter" contained specific statements which represented and suggested that the *calcarea fluorica 12x*, *ferrum phosphate 12x*, *silicea 12x*, and *kali muriaticum* would cure all skin diseases and chronic ailments; that the leaflets entitled "Letter No. 18" contained specific statements which represented and suggested that the *ferrum phosphate 6x*, *calcarea fluorica 6x*, *silicea 6x*, *kali muriaticum*, *kali phosphate*, *magnesia phosphate 3x*, and *calcarea phosphate* constituted a treatment for Hodgkin's disease; that the *natrum sulfate*, *calcarea phosphate*, *ferrum phosphate 6x*, *kali phosphate*, and *magnesia phosphate 3x* constituted a treatment for diabetes; that the *calcarea phosphate*, *ferrum phosphate 6x*, *kali phosphate*, *kali sulfate*, *natrum sulfate*, and *silicea 6x* constituted a treatment for asthma; that the *calcarea fluorica 6x* and *kali phosphate* constituted a treat-

ment for high blood pressure and many heart conditions; that the *silicea*, *ferrum phosphate*, and *kali sulfate* would cure sinus infections; that the *kali phosphate*, *magnesia phosphate 3x*, and *kali muriaticum* would restore impaired circulation to normal; and that the *magnesia phosphate*, *kali phosphate*, and *ferrum phosphate* would cure shingles.

The booklets entitled "Supplement Letter No. 19" contained specific statements which represented and suggested that the *magnesia phosphate* constituted a remedy for coronary thrombosis; that the *kali phosphate*, *ferrum phosphate*, and *calcarea phosphate* would cure Bright's disease; that the *natrum phosphate* and *natrum sulfate* constituted a remedy for gallbladder attack; that the *kali sulfate* would cure psoriasis; and that the *calcarea fluorica*, *kali phosphate*, and *ferrum phosphate* would bring high blood pressure back to normal in most cases.

The booklets entitled "Supplement Letter No. 6" contained specific statements which represented and suggested that the *ferrum phosphate* would afford relief and a possible cure for asthma and that the *calcarea fluorica*, *calcarea phosphate*, and *calcarea sulfate* would relieve and cure eczema and other skin ailments.

The above-mentioned statements, both general and specific, were false and misleading since the articles, singly or in combination, did not constitute adequate and effective cure, mitigation, treatment, and prevention of the diseases and conditions stated and implied, and the articles would not fulfill the promises of benefit made for them.

The articles were alleged to be misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 29, 1954. Default decree of condemnation and destruction.

4335. Misbranding of Weldona tablets. U. S. v. 492 Packages, etc. (F. D. C. No. 36175. Sample No. 26480–L.)

LIBEL FILED: December 7, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about September 17, 1952, from Cleveland, Ohio.

PRODUCT: 492 packages of *Weldona tablets* at Atlantic City, N. J., in possession of George S. Bross, doing business as Weldona, Inc., together with a number of form letters entitled "Dear Friend."

RESULTS OF INVESTIGATION: The product originally was shipped in bulk, and after its receipt by the consignee, it was repackaged and relabeled with the Weldona label. The form letters were caused to be printed by the consignee and were distributed in the mail to his customers.

LABEL, IN PART: (Package) "Weldona This package contains 65 tablets. Active ingredients: Sodium Salicylate 2½ grains, Powdered Extract of Cimicifuga ⅛ grain, Powdered Extract of Pokeroot (Phytolacca) ⅛ grain. For The Relief Of The Discomfort Of Muscular Aches And Pains Distributed By: Weldona, Inc., Atlantic City, N. J."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned form letters accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for rheumatism, arthritis, and sciatica. The article was not an adequate and effective treatment for such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: February 15, 1954. Weldona, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond, conditioned that the form letters be destroyed under the supervision of the Department of Health, Education, and Welfare.

4336. Misbranding of Massarelli's Salnate tablets. U. S. v. 6 Dozen Cartoned Bottles * * *. (F. D. C. No. 34669. Sample No. 51391–L.)

LIBEL FILED: February 17, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about January 3, 1953, by Manhattan Drug Co., Inc., from Brooklyn, N. Y.

PRODUCT: 6 dozen cartoned bottles of *Massarelli's Salnate tablets* at Bayonne, N. J.

LABEL, IN PART: (Carton and bottle) "Massarelli's Salnate For Relief of Symptoms Arthritis Rheumatism Active Ingredients: Calcium Succinate Acetylsalicylic Acid Ascorbic Acid 5 mg. Thiamin Chloride 1 mg. * * * 100 Tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label, the bottle carton, and on a counter display box were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritis, rheumatism and lumbago.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since aspirin was an active ingredient of the article and was declared as acetylsalicylic acid, which is not its common or usual name.

DISPOSITION: Manhattan Drug Co., Inc., appeared as claimant and filed an answer denying the allegations of the libel. A request for answers to written interrogatories thereafter was served by the Government upon the claimant. The claimant failed to object or respond to such interrogatories within the time provided by the Federal Rules of Civil Procedure. Accordingly, on March 8, 1954, the court ordered that the Government's motion to strike the claimant's pleadings be granted. On the same day, namely, March 8, 1954, the court entered a decree of condemnation and ordered that the product be destroyed.

4337. Misbranding of concentrated extract of alfalfa. U. S. v. 6¼ Cases, etc. (F. D. C. No. 35338. Sample No. 64598–L.)

LIBEL FILED: July 6, 1953, Western District of Washington.

ALLEGED SHIPMENT: On or about January 16, 1953, by Lucerne Laboratories of Utah, from American Fork, Utah.

PRODUCT: 6¼ cases, each case containing 24 8-ounce bottles, of *concentrated extract of alfalfa* at Seattle, Wash., together with a number of circulars entitled "Lucerne (Lucerne is the Old World name for Alfalfa)."

LABEL, IN PART: (Bottle) "Lucerne Concentrated extract of alfalfa (Medicago Sativa). It is a Dietary Supplement * * * One teaspoonful (5 mls) contains: 12.5 Mg. Calcium, 12 Mg. Phosphorus, 0.00586 Mg. Iron, 0.0069 Mg. Iodine * * * Lucerne contains sucrose which (in the process) is converted to Delta-Glucose and Fructose" or "Lucerne Concentrated extract of alfalfa, containing Cobalt, the vital element in Vitamin B_{12}. The Cobalt is from specially fertilized alfalfa, not a Pharmaceutical—and Sucrose which (in the process) is converted to Delta-Glucose and Fructose * * * It is a Beverage Food Supplement."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned circular accompanying the article were false and misleading. The statements represented and suggested that the article was effective to overcome fatigue and to treat rheumatism, arthritis, neurasthenia, exhaustion, and general debility, whereas the article was not effective for such purposes.

DISPOSITION: March 12, 1954. Default decree of condemnation and destruction.

4338. Misbranding of Nervosan device. U. S. v. 60 Devices, etc. (F. D. C. No. 34595. Sample No. 24089–L.)

LIBEL FILED: January 8, 1953, District of New Jersey.

ALLEGED SHIPMENT: The devices were imported in 1934 or 1935 by Josef Cornely, from the Medico Co., Munich, Germany, to Newark, N. J.

PRODUCT: 60 *Nervosan devices* at Newark, N. J., in possession of Josef Cornely, together with a number of booklets entitled "Nervosan—The New Way" and a number of 4-page illustrated leaflets containing statements relating to the device. The booklets and leaflets were printed in Newark, N. J., for Josef Cornely.

The device consisted essentially of an induction coil of interrupting type for the production of a chopped high-voltage and current. The device was capable also of producing ozone.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklets and leaflets accompanying the device were false and misleading. The statements represented and suggested that the device would insure against the proverbial discomfort of old age; that it was effective in the treatment of high blood pressure, anemia, diabetes, stomach troubles, rheumatism, exhaustion and general breakdown, hardening of the arteries, heart trouble, nerve derangements, paralysis, swollen ankles, varicose veins, growths, emaciation, excessively fatty condition, inflammations of the brain and chest, deficient hearing, epilepsy, inflammation of the eyes, gallbladder ailments, goiter, gout, lumbago, hemorrhoids, ulcers of the stomach and intestines, dropsy, neurasthenia, open legs, sores, infantile paralysis, stiff joints, sexual incompetence, pyorrhea, tuberculosis, bronchitis, whooping cough, influenza, measles, scarlet fever, diphtheria, typhus, and pneumonia; that it would supply health-giving force, flooding the entire body with living organism in harmonious relationship with the human nerve system; that it would reinvigorate, soothe the nerves, clarify brain activity, effect healthful sleep, regenerate, restore and maintain health and vitality, afford resistance to disease, break up congestion and disease and convert them to normalcy of nerves, blood, organs, and glands, and liberate from pain; and that it was effective in the treatment of hay fever and sinus and respiratory afflictions, affections of the ears, nose, heart, liver, kidneys, pancreas, skin, and a sore spot in the shoulder. The device was not effective in the treatment of the conditions stated and implied, and it was not capable of fulfilling the promises of benefit made for it. The device was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: Josef Cornely, claimant, filed an answer denying that the device was misbranded, after which the Government served upon the claimant written interrogatories which the claimant failed to answer. Thereafter, on April 9, 1954, upon motion by the Government, the court ordered that the claimant's pleadings be stricken and default entered for failure to answer the interrogatories, and that the device under seizure be condemned and destroyed.

4339. Misbranding of electric massager. U. S. v. 18 Cartons, etc. (F. D. C. No. 34674. Sample No. 37509–L.)

LIBEL FILED: February 19, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about October 31, 1952, by the Republic Electric & Mfg. Corp., from New York, N. Y.

PRODUCT: 18 cartons, each containing 36 de luxe models, and 36 cartons, each containing 36 standard models, of *electric massagers* at Newark, N. J. The device consisted of a small electric motor in a metal case with a rubber suction-type attachment that would vibrate. The de luxe model of the device had an anodized aluminum case, and the standard model had a case which appeared to be chrome plated.

LABEL, IN PART: (Device) "Electric Massager, 110–120 V, 50–60 cycle, 116 amps—14 watts."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a leaflet entitled "Reduce—Keep Slim at Home * * * Use Electric Spot Reducer," which was shipped with the device, were false and misleading. The statements represented and suggested that the device was effective to reduce and keep one slim and to cause the removal of fat from a part or area of the body. The device was not effective for such purposes.

DISPOSITION: Joseph J. Pinkus, Newark, N. J., appeared as claimant and filed an answer denying that the device was misbranded. A set of written interrogatories was served thereafter upon the claimant by the Government. The claimant failed to answer the interrogatories, and on April 9, 1954, the court entered a default decree of condemnation and destruction. On April 27, 1954, an amended decree was entered providing for the delivery of 6 devices to the the Food and Drug Administration.

4340. Misbranding of Miracle hearing aid. U. S. v. 500 Devices, etc. (F. D. C. No. 35630. Sample No. 66197–L.)

LIBEL FILED: September 16, 1953, Northern District of Illinois.

ALLEGED SHIPMENT: On or about May 9, 1952, by Miracle Hearing Aid, Inc., from East Orange, N. J.

PRODUCT: 500 devices known as *Miracle hearing aid* at Chicago, Ill., in possession of Edward S. Nickerson, doing business as Miracle Hearing Aid of Illinois, together with a number of brochures entitled "Sensational New Miracle Hearing Aid" and a number of leaflets entitled "A Modern Arabian Nights Story," "Instructions and Guide on Using & Handling Miracle Hearing Aid Efficiently," and "Customer's Purchase Agreement."

The device consisted of a piece of wire twisted into the shape of a miniature tuning fork, and rubber discs with perforated centers into which the wire was to be inserted.

RESULTS OF INVESTIGATION: The above-mentioned leaflets were printed at Chicago, Ill., for use by the consignee in connection with the marketing of the device.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned brochures and leaflets accompanying the device were false and misleading. The statements represented and suggested that the device was effective for enabling deaf persons and those suffering from impaired hearing to hear normally, whereas the device was not effective for such pur-

pose. The device was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: January 11, 1954. Default decree of condemnation. The court ordered that 36 devices and their labeling be delivered to the Food and Drug Administration and that the remainder of the devices and labeling be destroyed.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4321 TO 4340

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4321, 4324, 4333) Prosecution contested.
[2] (4327) Seizure contested. Contains opinion of the court.

[1] (4321, 4324, 4333) Prosecution contested.

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[2] (4327) Seizure contested. Contains opinion of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1939

D. D. N. J., F. D. C. 4341–4360 Issued April 1955

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4341–4360

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 30, 1955.*

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*For drug in violation of prescription labeling requirements, see No. 4348.

334460—55

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4341. Misbranding of methantheline bromide tablets, penicillin G potassium tablets, thyroid tablets, and tablets containing a mixture of phenobarbital, hyoscyamine sulfate, atropine sulfate, and hyoscine hydrobromide. U. S. v. John W. Adams, Thomas C. Watson, and Cecil F. Elkin. Pleas of guilty. Fine of $100 against Defendant Adams, $300 against Defendant Elkin, and $100 against Defendant Watson, plus costs. (F. D. C. No. 35736. Sample Nos. 56977–L, 71051–L, 71060–L, 71064–L, 71071–L.)

INFORMATION FILED: November 19, 1953, Eastern District of Kentucky, against John W. Adams and Thomas C. Watson, partners in the partnership of Adams & Watson Drugs, Paris, Ky., and against Cecil F. Elkin, a pharmacist for the partnership.

NATURE OF CHARGE: On or about April 27 and June 1, 5, and 8, 1953, while a number of *methantheline bromide tablets, penicillin G potassium tablets, thyroid tablets,* and *tablets containing a mixture of phenobarbital, hyoscyamine sulfate, atropine sulfate, and hyoscine hydrobromide* were being held for sale at Adams & Watson Drugs, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Defendant Adams was charged with causing the dispensing of a quantity of the *tablets containing a mixture of phenobarbital, hyoscyamine sulfate, atropine sulfate, and hyoscine hydrobromide;* Defendant Elkin was charged with causing the dispensing of an additional quantity of such tablets and also the dispensing of the *methantheline bromide tablets* and the *penicillin G potassium tablets;* and Defendant Watson was charged with causing the dispensing of the *thyroid tablets.* Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: January 12, 1954. The defendants having entered pleas of guilty, the court fined Defendant Adams $100, Defendant Elkin $300, and Defendant Watson $100, plus costs.

4342. Misbranding of thyroid tablets and dextro-amphetamine sulfate tablets. U. S. v. Harold H. Loomis (Loomis Drug Store). Plea of guilty. Fine of $300, plus costs. (F. D. C. No. 35744. Sample Nos. 33199–L to 33201–L, incl.)

INFORMATION FILED: December 10, 1953, Northern District of Indiana, against Harold H. Loomis, trading as Loomis Drug Store, Angola, Ind.

NATURE OF CHARGE: On or about March 12 and April 2, 1953, while a number of *thyroid tablets* and *dextro-amphetamine sulfate tablets* were being held for sale at the Loomis Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: March 10, 1954. The defendant having entered a plea of guilty, the court fined him $300, plus costs.

4343. Misbranding of dextro-amphetamine sulfate tablets and pentobarbital sodium capsules. U. S. v. Travis E. Shankle (Lyons Drug Co.), Herbert C. Rehnberg, and Henry Rozeboom. Plea of nolo contendere by Defendant Shankle and pleas of guilty by Defendants Rehnberg and Rozeboom.

Fine of $200 against Defendant Shankle, $150 against Defendant Rozeboom, and $100 against Defendant Rehnberg, plus costs. (F. D. C. No. 35192. Sample Nos. 19888–L, 48448–L, 48455–L, 48456–L.)

INFORMATION FILED: November 2, 1953, Southern District of Iowa, against Travis E. Shankle, trading as the Lyons Drug Co., Clinton, Iowa, and Herbert C. Rehnberg and Henry Rozeboom, pharmacists.

NATURE OF CHARGE: On or about October 20 and November 13 and 14, 1952, while a number of *dextro-amphetamine sulfate tablets* and *pentobarbital sodium capsules* were being held for sale at the Lyons Drug Co., after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Defendant Shankle was charged with causing the acts of dispensing involved in each of the 4 counts of the information; Defendant Rehnberg was joined as a defendant in count 2; and Defendant Rozeboom was joined as a defendant in counts 3 and 4. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: March 22, 1954. Defendant Shankle having entered a plea of nolo contendere and the other defendants having entered pleas of guilty, the court imposed a fine of $200 against Defendant Shankle, $150 against Defendant Rozeboom, and $100 against Defendant Rehnberg, plus costs.

4344. Misbranding of amphetamine sulfate tablets and methamphetamine hydrochloride tablets. U. S. v. Robert F. Stephenson. Plea of guilty. Defendant placed on probation for 2 years. (F. D. C. No. 35751. Sample Nos. 70849–L, 70850–L.)

INFORMATION FILED: December 18, 1953, Northern District of Indiana, against Robert F. Stephenson,manager and pharmacist for Model Drugs, Inc., Marion, Ind.

NATURE OF CHARGE: On or about June 16, 1953, while a number of *amphetamine sulfate tablets* and *methamphetamine hydrochloride tablets* were being held for sale at Model Drugs, Inc., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: March 23, 1954. The defendant having entered a plea of guilty, the court placed him on probation for 2 years.

4345. Misbranding of methyltestosterone tablets and methantheline bromide tablets. U. S. v. Birt C. Camp. Plea of guilty. Defendant fined $1,000 and sentenced to 3 months in jail; jail sentence suspended and defendant placed on probation for 18 months. (F. D. C. No. 35765. Sample Nos. 69241–L, 69244–L, 69249–L, 69250–L.)

INFORMATION FILED: January 5, 1954, Northern District of Texas, against Birt C. Camp, a partner and pharmacist of Camp's Pharmacy, Plainview, Tex.

NATURE OF CHARGE: On or about June 13, 15, and 20, 1953, while a number of *methyltestosterone tablets* and *methantheline bromide tablets* were being held for sale at Camp's Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drugs.

Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: May 4, 1954. The defendant having entered a plea of guilty, the court fined him $1,000 and sentenced him to 3 months in jail, but suspended the jail sentence and placed him on probation for 18 months.

4346. Misbranding of Seconal Sodium capsules. U. S. v. Sidney Halpern. Plea of guilty. Fine of $200, plus costs. (F. D. C. No. 35562. Sample Nos. 70511–L, 70512–L.)

INFORMATION FILED: November 3, 1953, Eastern District of Kentucky, against Sidney Halpern, a pharmacist for the W. L. Foertmeyer Drugs, Bellevue, Ky.

NATURE OF CHARGE: On or about May 19 and 28, 1953, while a number of *Seconal Sodium capsules* were being held for sale at the W. L. Foertmeyer Drugs, after shipment in interstate commerce, Defendant Halpern caused a number of capsules of the drug to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: March 8, 1954. The defendant having entered a plea of guilty, the court fined him $200, plus costs.

4347. Misbranding of secobarbital sodium capsules. U. S. v. Jack L. Kramer and Hyman Fineman. Pleas of guilty. Fine of $1,000 and sentence of 3 months in jail against each defendant; jail sentence suspended and each defendant placed on probation for 6 months. (F. D. C. No. 35564. Sample Nos. 72308–L to 72310–L, incl.)

INDICTMENT RETURNED: September 28, 1953, District of Columbia, against Jack L. Kramer and Hyman Fineman, partners in the partnership of Simpson's Modern Pharmacy, Washington, D. C.

NATURE OF CHARGE: On or about August 12 and 17, 1953, the defendants caused quantities of *secobarbital sodium capsules* to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: February 26, 1954. The defendants having entered pleas of guilty, the court fined each defendant $1,000 and sentenced each to 3 months in jail. The court suspended the jail sentence and placed each defendant on probation for 6 months.

4348. Misbranding of Tasapan Pearls. U. S. v. 168 Bottles * * *. (F. D. C. No. 35411. Sample No. 66976–L.)

LIBEL FILED: September 10, 1953, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about April 8, 1952, and April 7, 1953, from Jersey City, N. J.

PRODUCT: 168 bottles of *Tasapan Pearls* at Philadelphia, Pa., in possession of Joseph Freiberg.

RESULTS OF INVESTIGATION: The product, after its receipt by the consignee at Philadelphia, Pa., was resold to Joseph Freiberg, in whose possession it was relabeled as set forth below.

LABEL, IN PART: (Bottle) "Caution—To Be Used Only By Or On The Prescription Of A Physician 25 Tasapan Pearls * * * A carefully prepared combination of pennyroyal, apiol, powdered ext. of ergot, aloin, savin, rue, and vegetable oil in a soft gelatin pearl."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to reveal the purposes for which the article was to be taken; and, Section 503 (b) (4), the article was a drug which was subject to Section 503 (b) (1) (B), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription." The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 24, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4349. Misbranding of pituitary tablets. U. S. v. 1 Bottle * * *. (F. D. C. No. 36288. Sample No. 82555-L.)

LIBEL FILED: January 14, 1954, Western District of New York.

ALLEGED SHIPMENT: On or about August 24, 1953, by Richlyn Laboratories, from Philadelphia, Pa.

PRODUCT: 1 bottle containing 10,000 *pituitary tablets* at Rochester, N. Y.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it did not state the conditions in which the article was to be used.

DISPOSITION: February 12, 1954. Default decree of condemnation and destruction.

4350. Misbranding of Triulcin tablets. U. S. v. 13 Cases, etc. (F. D. C. No. 36072. Sample No. 50541-L.)

LIBEL FILED: November 4, 1953, Southern District of New York.

ALLEGED SHIPMENT: On or about September 10, 1953, from Newark, N. J.

PRODUCT: *Triulcin tablets.* 13 cases, containing a total of 86,600 tablets, and 126 cartons, each carton containing 100 tablets and a leaflet entitled "Further Facts About Triulcin," at New Rochelle, N. Y., in possession of S. B. Leonardi & Co., Inc., together with an additional quantity of the leaflets and a number of empty cartons labeled in the same manner as the 126-carton lot.

RESULTS OF INVESTIGATION: When originally shipped from Newark, N. J., the tablets were contained in 15 cases, each containing 140 cellophane strips and each strip containing 50 tablets. Upon receipt of the tablets by the consignee, a portion of the shipment was repackaged into cartons, with the balance of the shipment, consisting of 13 cases, being held for repackaging into the above-mentioned empty cartons.

LABEL, IN PART: (Carton) "Triulcin Indicated for relief of stomach Ulcer Pains and discomfort due to excessive stomach acidity 100 Tablets * * * Active Ingredients: Hibiscus Esculentus, Water-soluble Chlorophyllin, Aluminum Hydroxide Gel, Magnesium Trisilicate, Excipients and Flavor. Average Dose: 10 tablets daily—2 on arising, 2 on retiring, and 2 after each meal (at

*See also No. 4348.

least one hour after the meal). Take with minimum amount of water. More rapidly effective when chewed before swallowing."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the carton label and on the above-mentioned leaflet accompanying the article contained in the cases and in the cartons were false and misleading. The statements represented and suggested that the article in the cases and cartons was an adequate and effective treatment for gastric and duodenal ulcers and would completely heal ulcer craters.

Further misbranding, Section 502 (f) (1), the labeling of the repackaged article contained in the cartons failed to bear adequate directions for use since the directions on the carton "Average Dose: 10 tablets daily—2 on arising, 2 on retiring, and 2 after each meal (at least one hour after the meal). Take with minimum amount of water. More rapidly effective when chewed before swallowing" were not adequate directions for use in the treatment of gastric and duodenal ulcers.

The article contained in the cases and as repackaged in the cartons was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 26, 1954. Torbert Laboratories, Inc., New Rochelle, N. Y., claimaint, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for the destruction of the labeled cartons and leaflets and the relabeling of the product under the supervision of the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4351. Adulteration of oxygen. U. S. v. John Suydam (Newburgh Oxygen Co.), and George H. Gordon. Pleas of guilty. Fine of $750 against Defendant Suydam and $150 against Defendant Gordon. Jail sentence of 6 months against Defendant Suydam suspended and defendant placed on probation for 6 months; jail sentence of 3 months against Defendant Gordon also suspended and this defendant placed on probation for 3 months. (F. D. C. No. 30044. Sample Nos. 73341–K, 73343–K, 74527–K.)

INFORMATION FILED: February 7, 1952, Southern District of New York, against John Suydam, trading as the Newburgh Oxygen Co., Newburgh, N. Y., and George H. Gordon, an employee in the business.

ALLEGED VIOLATION: At a time prior to April 25, 1950, while a large metal cylinder of carbon dioxide was being held for sale at the Newburgh Oxygen Co., after shipment in interstate commerce, the defendants repacked a quantity of the carbon dioxide into a small metal cylinder and attached to the cylinder a tag containing the printed and graphic matter set forth below; and, on or about April 25, 1950, the defendants sold and delivered the small metal cylinder containing carbon dioxide, and in the invoice of such sale, represented that this metal cylinder contained *oxygen*. It was alleged that such acts of repacking and labeling of the article in the small metal cylinder resulted in the article in the small cylinder being adulterated.

LABEL, IN PART: (Tag) "Newburgh Oxygen Co. Newburgh, N. Y. Phone 2745 Carbon Dioxide——% Oxygen Only——% Cyl. No.—— Filled 4/25/50 Empty ——Tear Off here when empty Full."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), carbon dioxide had been substituted for *oxygen*, which the article was represented to be.

DISPOSITION: April 29, 1954. The defendants having entered pleas of guilty, the court fined Defendant Suydam $750 and Defendant Gordon $150. Defendant Suydam also was sentenced to 6 months in jail and Defendant Gordon to 3 months, but both jail sentences were suspended and Defendant Suydam was placed on probation for 6 months and Defendant Gordon for 3 months.

4352. Adulteration and misbranding of Neo-Lifo B–12 and Livo–12–Crude. U. S. v. American Bio-Chemical Corp., Abraham Rothenberg, and Vincent M. Leuterio (indictment). U. S. v. Al G. Johns (information). Pleas of guilty. Fine of $400 against corporation and $50 against each individual. (F. D. C. No. 33769. Sample Nos. 33249–L, 42312–L, 53016–L.)

INDICTMENT RETURNED: Between August 12 and October 1, 1953, Southern District of California, against the American Bio-Chemical Corp., Los Angeles, Calif., Abraham Rothenberg, production manager of the corporation, and Vincent M. Leuterio, bacteriologist of the corporation.

INFORMATION FILED: December 14, 1953, Southern District of California, against Al G. Johns, president and treasurer of the American Bio-Chemical Corp.

ALLEGED VIOLATION: On or about July 3 and 14, 1952, the defendant corporation and each of the individual defendants caused to be introduced into interstate commerce, at Los Angeles, Calif., for delivery to Detroit, Mich., and Herrin, Ill., a quantity of *Neo-Lifo B–12* which was adulterated and misbranded.

In addition, the defendant corporation and Defendant Rothenberg and Defendant Leuterio, on or about May 14, 1952, gave to a firm engaged in the business of shipping drugs in interstate commerce, at Palo Alto, Calif., an invoice containing a guaranty which provided that the *Livo–12–Crude* listed in the invoice was neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act. On or about May 14, 1952, the defendant corporation and Defendant Rothenberg and Defendant Leuterio delivered to the holder of the guaranty, at Palo Alto, Calif., a quantity of *Livo–12–Crude* which was adulterated and misbranded.

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality and purity of the articles fell below that which they were represented to possess. The articles were represented to be sterile, whereas they were not sterile but were contaminated with viable micro-organisms.

Misbranding, section 502 (a), the label statement "Sterile Solution" appearing on the label of each of the articles was false and misleading since the articles were not sterile solutions but were solutions contaminated with viable micro-organisms.

DISPOSITION: January 4, 1954. The defendants having entered pleas of guilty, the court fined the corporation $400 and each individual defendant $50.

4353. Adulteration and misbranding of digitoxin tablets. U. S. v. 36 Bottles * * *. (F. D. C. No. 36225. Sample No. 39649–L.)

LIBEL FILED: January 7, 1954, Southern District of California.

ALLEGED SHIPMENT: On or about September 28, 1953, by Richlyn Laboratories, from Philadelphia, Pa.

PRODUCT: 36 1,000-tablet bottles of *digitoxin tablets* at Los Angeles, Calif. Examination showed that the product contained 0.15 mg. of cardioactive gly-

cosides per tablet, corresponding to only 75 percent of the declared amount of digitoxin.

LABEL, IN PART: (Bottle) "Tablets Digitoxin USP 0.2 Mg."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article was a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard. The standard requires that *digitoxin tablets* contain not less than 90 percent of the labeled amount of digitoxin, whereas the article contained not more than 75 percent of the labeled amount of cardioactive glycosides calculated as digitoxin.

Misbranding, Section 502 (a), the label statement "Tablets Digitoxin USP 0.2 Mg." was false and misleading as applied to the article, which contained not more than 75 percent of the declared amount of digitoxin per tablet.

DISPOSITION: March 9, 1954. Default decree of condemnation and destruction.

4354. Adulteration and misbranding of C-Tone. U. S. v. 17 Cases, etc. (F. D. C No. 35417. Sample No. 17646-L.)

LIBEL FILED: September 10, 1953, Southern District of California.

ALLEGED SHIPMENT: On or about July 17, 1953, by Byrne Products, Inc., from New York, N. Y.

PRODUCT: 17 cases, each containing 12 bottles, of *C-Tone* at Los Angeles, Calif., together with a number of leaflets entitled "Which Of These Dread Killers Threaten Your Advancing Years?" a number of placards headed "For That Pep of Health Natural C-Tone," and a number of placards entitled "Which of These Conditions Threaten Your Advancing Years?"

Analysis showed that the product contained less than 0.04 milligram of niacin per 4 tablespoons.

LABEL, IN PART: (Bottle) "Rich In Activated Enzymes C-Tone The Natural Vitamin C Tonic * * * Four tablespoons furnish: * * * Natural Niacin . . . 0.08 mg. * * * 8 Fl. Oz. Net."

NATURE OF CHARGE: Adulteration, Section 501 (c) the strength of the article differed from that which it purported and was represented to possess, namely, 0.08 milligram of niacin per 4 tablespoons.

Misbranding, Section 502 (a), the label statement "Four tablespoons furnish: * * * Natural Niacin . . . 0.08 mg." was false and misleading as applied to the article, which contained less than 0.08 milligram of niacin per 4 tablespoons; the label statements "Rich In Activated Enzymes" and "Vitamin C Tonic" were false and misleading since they represented and suggested that the article was of nutritional and therapeutic value because of enzyme content and that it was effective as a tonic, whereas the article was of no value because of its enzyme content and was not a tonic; and certain statements on the above-mentioned leaflets and placards accompanying the article were false and misleading since they represented and suggested that the article was an adequate and effective treatment for high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, and dizzy spells, and that it was effective to provide energy and improve digestion, whereas the article was not an adequate and effective treatment for such conditions and would not fulfill the promises of benefit stated and implied.

DISPOSITION: May 25, 1954. Byrne Products, Inc., having filed a claim and answer and later having withdrawn such claim and answer, judgment of condemnation was entered and the court ordered that the product be destroyed.

4355. Adulteration and misbranding of rubber prophylactics. U. S. v. 32 Gross * * *. (F. D. C. No. 36229. Sample No. 60129–L.)

LIBEL FILED: January 8, 1954, Northern District of Georgia.

ALLEGED SHIPMENT: On or about October 5, 1953, by the Chemical Latex Exchange, from Philadelphia, Pa.

PRODUCT: 32 gross of *rubber prophylactics* at Atlanta, Ga. Examination of 144 units of the product showed that 8 were dried out and could not be unrolled without damage and were therefore unsuitable for use.

LABEL, IN PART: "Zenith Lubri-Pak."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "For the prevention of disease" were false and misleading as applied to the article, which was dried out and could not be unrolled without damage.

DISPOSITION: February 3, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4356. Misbranding of Gramer's Sulgly-Minol. U. S. v. 21 Bottles * * * (and 1 other seizure action). (F. D. C. Nos. 36215, 36216. Sample Nos. 14749–L, 14750–L.)

LIBELS FILED: January 4, 1954, District of Colorado.

ALLEGED SHIPMENT: During the last 6 months of the year 1953, by Walter W. Gramer, from Minneapolis, Minn.

PRODUCT: 127 bottles of *Gramer's Sulgly-Minol* at Denver, Colo., together with a number of circulars headed "Arthritis Hundreds Claim Its Grip Broken" and "A Light Should Not Be Hidden Testimonials * * * we have received from people who have been relieved from the pains of Arthritis and Rheumatism by using 'Sul-Gly Minol.'"

LABEL, IN PART: (Bottle) "4 Fl. Ozs. Gramer's Sulgly-Minol * * * A solution of Sulphur, Glycerine, Sulphurated Lime and Isopropyl Alcohol 6% * * * For the relief of muscular pains and soreness, add 1 tablespoon to 1 quart of warm water for foot bath, also apply direct to soles of feet. Add one-fourth bottle to tub of water for sulphur tub bath."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned circulars accompanying the article were false and misleading. The statements represented and suggested that the article, diluted with water and used as a foot bath, applied to the soles of the feet, or used as a tub bath, was an adequate and effective treatment for arthritis, pain in the legs, hips, back, and arms, ailments of a rheumatic nature, and stiffness and soreness of legs and knees. The article, when used as directed, was not an ade-

*See also Nos. 4350, 4352–4355.

quate and effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: March 3, 1954. Default decrees of condemnation and destruction.

4357. **Misbranding of Ozonator device. U. S. v. 2 Cartoned Devices, etc.** (F. D. C. No. 35401. Sample No. 65445–L.)

LIBEL FILED: September 15, 1953, District of South Dakota.

ALLEGED SHIPMENT: During the month of June 1953, by A. L. Gesche, from Spokane, Wash.

PRODUCT: 2 cartoned *Ozonator devices* at Lemmon, S. Dak., together with a number of leaflets entitled "Northwest Ozonator" and a booklet entitled "Ozone God's Gift to Humanity."

The device consisted of 8 tubes, together with the electrical equipment necessary to produce an electrical discharge through the tubes when the device was connected to an appropriate power source.

LABEL, IN PART: (Sticker attached to device) "A. C. 60 Cycle 115–20 V. Ozonator Guaranteed for 1 year against defects Northwest Ozonator Co. W. 1610 Gardner Ave. Spokane 11, Washington."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets and booklet accompanying the device were false and misleading. The statements represented and suggested that the device was an adequate and effective treatment for all kinds of ailments and for many so-called incurable diseases; that its use would increase the number of red blood corpuscles; that it was an effective treatment for asthma and all diseases of the respiratory organs; that it would dissolve and break up abnormal deposits such as arthritis and nephrolithiasis or cholelithiasis; that the device was an adequate and effective treatment for anemia, pernicious anemia, colitis, arthritis, sinusitis, head colds, cardiovascular renal disease, tuberculosis, and rheumatism; and that it would improve the general health and make one more active physically, psychologically, and sexually. The device was not an adequate and effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: April 21, 1954. Default decree of condemnation. The court ordered that the devices and accompanying labeling be delivered to the Food and Drug Administration.

4358. **Misbranding of Miracle hearing aid. U. S. v. 237 Devices, etc.** (F. D. C. No. 35413. Sample No. 55168–L.)

LIBEL FILED: August 31, 1953, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about July 28, 1952, by Miracle Hearing Aid, Inc., from East Orange, N. J.

PRODUCT: 237 unassembled devices called the *Miracle hearing aid* at Sheboygan, Wis., together with a number of brochures and window placards designated as "Sensational, New Miracle Hearing Aid."

When assembled, the device consisted of a piece of wire, twisted into the shape of a miniature tuning fork, and rubber discs with perforated centers into which the wire was to be inserted.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned brochures and placards were false and misleading. The statements represented and suggested that the device was effective for ena-

bling deaf persons and those suffering from impaired hearing to hear normally, whereas the device was not effective for such purposes.

DISPOSITION: March 17, 1954. Default decree of condemnation and destruction.

4359. Misbranding of Miracle hearing aid. U. S. v. 39 Devices * * *. (F. D. C. No. 35369. Sample No. 59523-L.)

LIBEL FILED: July 31, 1953, Northern District of Illinois.

ALLEGED SHIPMENT: The devices were shipped on or about April 6, 1953, or on other dates unknown, by the Miracle Hearing Aid Co., from Newark, N. J., to Miami, Fla., consigned to A. E. Komes, and were thereafter reshipped by A. E. Komes from Miami, Fla., to Aurora, Ill.

PRODUCT: 39 devices called the *Miracle hearing aid* at Aurora, Ill. The device consisted of a piece of wire, twisted into the shape of a miniature tuning fork, and rubber discs with perforated centers into which the wire was to be inserted.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "Sensational, New Miracle Hearing Aid" were false and misleading. The statements represented and suggested that the device provided an adequate and effective aid to auditory acuity of deaf persons, whereas the device did not provide an adequate and effective aid to the auditory acuity of deaf persons. The device was misbranded when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce.

DISPOSITION: September 24, 1953. Default decree of condemnation. The court ordered that the devices be turned over to the Food and Drug Administration.

DRUG FOR VETERINARY USE

4360. Misbranding of udder ointment. U. S. v. 9 Cases * * *. (F. D. C. No. 36064. Sample No. 83262-L.)

LIBEL FILED: October 28, 1953, Northern District of Illinois.

ALLEGED SHIPMENT: On or about April 17, 1953, by the Peerless Serum Co., from Kansas City, Mo.

PRODUCT: 9 cases, each containing 12 jars, of udder ointment at Chicago, Ill.

LABEL, IN PART: (Jar) "Udder Ointment 1 lb. net wt. Contains: Phenol, Methyl Salicylate, Oil Eucalyptus, Turpentine, Lanolin, Petrolatum, Biebrich Scarlet * * * Dosage For local application of non-tubercular inflammations of the udder of both cows and mares."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the jar label, contained statements which represented and suggested that the article was an adequate and effective treatment for mastitis of cows and mares, which statements were false and misleading since the article was not an adequate and effective treatment for such conditions.

DISPOSITION: February 9, 1954. Default decree of condemnation and destruction.

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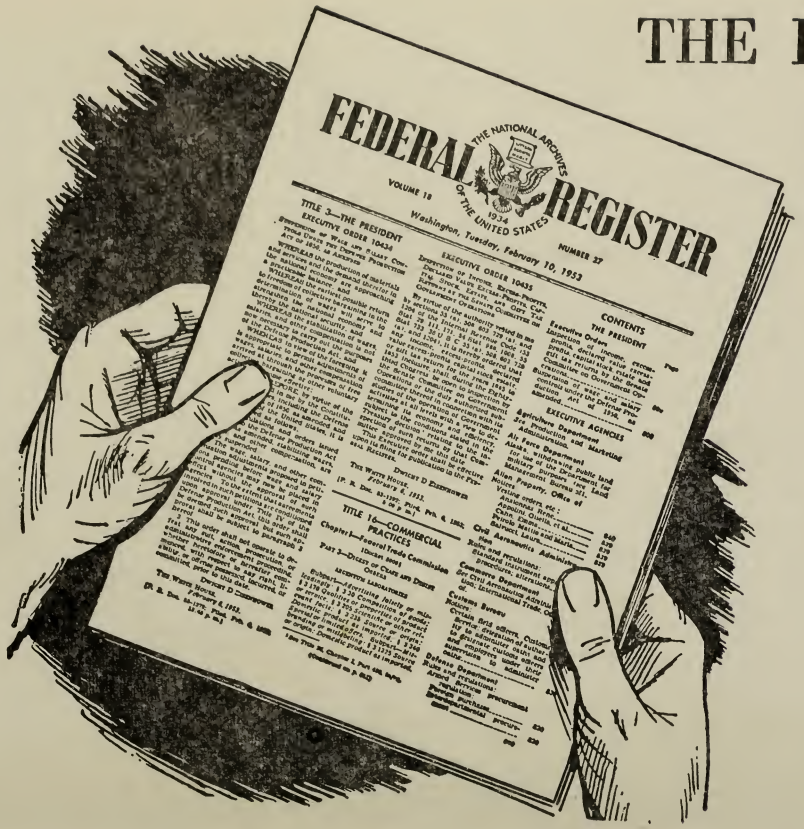

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D. D. N. J., F. D. C. 4361–4380 Issued May 1955

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4361–4380

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C. *April 26, 1955.*

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DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4361. Misbranding of penicillin G potassium tablets. U. S. v. 39 Bottles, etc. (F. D. C. No. 36452. Sample Nos. 52959–L, 52960–L.)

LIBEL FILED: March 16, 1954, Eastern District of New York.

ALLEGED SHIPMENT: On or about November 20, 1953, from Terre Haute, Ind.

PRODUCT: *Penicillin G potassium tablets.* 39 100-tablet bottles and 60 1,000-tablet bottles of 50,000-unit tablets and 19 100-tablet bottles and 35 1,000-tablet bottles of 100,000-unit tablets at Woodside, N. Y., in possession of Henry Schein Physicians & Hospital Supplies.

RESULTS OF INVESTIGATION: The tablets were shipped in bulk from Terre Haute, Ind., and upon their receipt by the consignee, were repackaged and relabeled.

LABEL, IN PART: (Bottle) "Buffered Penicillin Tablets Crystalline G Potassium."

NATURE OF CHARGE: Misbranding, Section 502 (1), the article purported to be and was represented as a drug composed wholly or partly of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 19, 1954. Henry Schein, Woodside, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for the purpose of obtaining certification from the Food and Drug Administration and for relabeling the product.

4362. Misbranding of penicillin-dihydrostreptomycin bougies. U. S. v. 65 Vials, etc. (F. D. C. No. 36176. Sample Nos. 83393–L, 83394–L.)

LIBEL FILED: December 8, 1953, District of Minnesota.

ALLEGED SHIPMENT: On or about January 26 and September 22, 1953, by Veta-Vite Products, Inc., from Buffalo, N. Y.

PRODUCT: *Penicillin-dihydrostreptomycin bougies.* 65 vials and 11 packages, each vial and package containing 25 bougies, at Minneapolis, Minn.

NATURE OF CHARGE: Misbranding, Section 502 (1), the article purported to be and was represented as a drug composed partly of penicillin and streptomycin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and no such certificate or release was in effect with respect to the article.

DISPOSITION: March 8, 1954. Default decree of destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4363. Misbranding of penicillin G potassium, dihydrostreptomycin sulfate, penicillin G potassium tablets, secobarbital sodium capsules, and tablets containing a mixture of sulfathiazole, sulfadiazine, and sulfamerazine. U. S. v. Orville Jackson (Eagle Drug Store). Plea of nolo contendere. Sentence of 1 hour's imprisonment suspended. (F. D. C. No. 35760. Sample Nos. 76131–L to 76135–L, incl.)

INFORMATION FILED: January 26, 1954, District of Idaho, against Orville Jackson, trading as Eagle Drug Store, Eagle, Idaho.

NATURE OF CHARGE: On or about June 17, 22, and 30, 1953, while quantities of the above-mentioned drugs were being held for sale at the Eagle Drug Store, after shipment in interstate commerce, the defendant caused quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: February 8, 1954. The defendant having entered a plea of nolo contendere, the court imposed a sentence of 1 hour's imprisonment. The sentence was suspended.

4364. Misbranding of dextro-amphetamine sulfate tablets and pentobarbital sodium capsules. U. S. v. Lloyd Mayswinkle (Lloyd's Drug Store), and Harry J. Roberts. Pleas of guilty. Each defendant fined $100 and placed on probation for 2 years. (F. D. C. No. 35772. Sample Nos. 61746–L, 61747–L, 61750–L, 61751–L.)

INFORMATION FILED: January 26, 1954, District of Kansas, against Lloyd Mayswinkle, trading as Lloyd's Drug Store, Kansas City, Kans., and Harry J. Roberts, an employee in the store.

NATURE OF CHARGE: On or about October 13 and 14, 1953, while a number of *dextro-amphetamine sulfate tablets* and *pentobarbital sodium capsules* were being held for sale at Lloyd's Drug Store, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Defendant Mayswinkle was charged with causing the act of dispensing alleged in each of the four counts of the information, and Defendant Roberts was joined as a defendant in three of the counts. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: February 4, 1954. The defendants having entered pleas of guilty, the court fined each defendant $100 on count 1 of the information, suspended the imposition of sentence on the remaining counts, and placed each defendant on probation for 2 years.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4365. Misbranding of penicillin G potassium. U. S. v. 83 Vials * * *. (F. D. C. No. 36303. Sample No. 83501–L.)

LIBEL FILED: February 2, 1954, Southern District of Iowa.

ALLEGED SHIPMENT: During November or December 1953, by the Gland-O-Lac Co., from Omaha, Nebr.

PRODUCT: 83 vials of *penicillin G potassium* at Des Moines, Iowa.

LABEL, IN PART: "One Million Units Crystalline Penicillin G Potassium Salt 20 cc. Size Vial * * * For Parenteral Administration * * * Caution: Federal Law Prohibits Dispensing Without Prescription."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 503 (b) (4), the article was not intended for use by man, and the label bore the statement "Caution: Federal Law Prohibits Dispensing Without Prescription."

DISPOSITION: March 5, 1954. Default decree of condemnation and destruction.

4366. Misbranding of ovarian substance, suprarenal cortex, and spleen substance. U. S. v. 4 Bottles, etc. (F. D. C. No. 36443. Sample Nos. 39655–L to 39657–L, incl.)

LIBEL FILED: March 16, 1954, Southern District of California.

ALLEGED SHIPMENT: On or about November 13, 1952, and January 16, September 17, and November 9, 1953, by Wilson & Co., Inc., from Chicago, Ill.

PRODUCT: 4 bottles of *ovarian substance*, 16 bottles of *suprarenal cortex*, and 1 bottle of *spleen substance* at Los Angeles, Calif.

LABEL, IN PART: (Bottle) "100 5 Gr. Ct. Item No. 73 Ovarian Substance N. F. VIII * * * Dose: As administered by the physician," "100 Caps. Item No. 181 Suprarenal Cortex 2 Grains The dried and defatted product after removal of a major portion of the medulla. * * * Caution: Federal law prohibits dispensing without prescription," and "100 Caps. Item No. 164 Spleen Substance 5 Gr. Each capsule contains five grs. dried and partially defatted spleen. Caution: Federal law prohibits dispensing without prescription."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use; and, Section 503 (b) (4), the labels of the articles prior to dispensing bore the statement "Caution: Federal law prohibits dispensing without prescription," and the articles were drugs to which Section 503 (b) (1) did not apply.

DISPOSITION: April 8, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS *

4367. Misbranding of Elemin multiple vitamin and mineral tablets. U. S. v. 15 Cases * * *. (F. D. C. No. 36189. Sample No. 61927–L.)

LIBEL FILED: On or about December 15, 1953, Western District of Missouri.

ALLEGED SHIPMENT: On or about July 27, August 25, and October 21, 1953, from Berkeley, Calif.

PRODUCT: 15 cases, each containing 24 retail cartons, of *Elemin multiple vitamin and mineral tablets* at Kansas City, Mo., in possession of G & J Distributors.

LABEL, IN PART: (Carton) "Contents 360 Tablets * * * Elemin G & J Multiple Vitamins Supreme Formula * * * 240 Mineral Tablets As a Source of the Minerals Iron and Iodine Contains: Iodine and Iron as naturally present in dehydrated kelp, iron gluconate and a sedimentary mineral deposit with excipients, and artificial color added to coating. 4 Tablets per day (suggested daily intake) will provide: Iodine—not less than 0.2 Mg. 200% minimum daily adult requirement Iron—not less than 30.0 Mg. 300% minimum daily adult requirement * * * 120 Multiple Vitamin Tablets 2 Tablets daily will supply: Vitamin A ..... 25,000 USP Units Vitamin D ..... 1200 USP Units Vitamin B_1 ..... 8.0 Mg. Vitamin B_2 ..... 5.0 Mg. Vitamin B_6 ..... 2.0 Mg. Vitamin B_{12} ..... 3.0 Mcg. Vitamin C ..... 150.0 Mg. Vitamin E ..... 10.0 Mg. Niacin ..... 10.0 Mg. Niacinamide ..... 40.0 Mg. Calcium Pantothenate 10.0 Mg. Inositol ..... 10 Mg. Choline ..... 10.0 Mg. Para Aminobenzoic Acid 10.0 Mg. Rutin ..... 1.0 Mg. Folic Acid ..... 1.0 Mg. Chlorophyll ..... 1.0 Mg. Conc. Beef Liver Extract 65.0 Mg. * * * Alfalfa Concentrate, Excipients, Binders, and Artificial Color in Coating. * * * Supreme Formula is packaged in sanitary, hermetically sealed

*See also Nos. 4365, 4366.

Pocket Paks, each containing 2 Elemin Mineral Tablets and 1 G & J Multiple Vitamin Tablet."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the label of the article failed to bear directions for use in the treatment of ulcers, high blood pressure, arthritis, diabetes, polio, infantile paralysis, cancer, dormant glands, migraine headache, allergic reactions, thyroid trouble, and diarrhea, which were the conditions for which the article was intended and offered in oral statements made on November 4, 1953, by Roy M. Buck, operator of G & J Distributors, while promoting the sale of the article. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 4, 1954. Default decree of condemnation and destruction.

4368. Misbranding of Nu-Mineral capsules. U. S. v. 3 Cases * * *. (F. D. C. No. 36350. Sample No. 82454–L.)

LIBEL FILED: January 19, 1954, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 28, 1953, from Clarksburg, W. Va. This was a return shipment.

PRODUCT: 3 cases, each containing 216 42-capsule bottles, of *Nu-Mineral capsules* at Sharon, Pa.

LABEL, IN PART: (Bottle) "Nu-Mineral Three Capsules Supply Dicalcium Phosphate, USP ..... 975 mgm. 30% Ferrous Sulfate, Dried, USP ..... 135 mg. 400% Potassium Iodide, USP ..... .45 mg. 300% Manganese Sulfate, H2O, CP ..... 4.5 mg. Cobalt Nitrate, 6 H2O, CP ..... 1.5 mg. Sodium Molybdate, 2 H2O, CP ..... 3.0 mg. Copper Sulfate, USP ..... 3.0 mg. Zinc Sulfate, USP ..... 4.2 mg. Magnesium Sulfate, USP ..... 97.5 mg. Aloin, USP ..... 8. mg. Vitamin B-12, USP ..... 3 mcgm. Distributed by Penn-Art Products, Sharon, Pa."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of stomach ailments, weak kidneys, rheumatic pains, arthritis, neuritis, headaches, toxins, bloating, weak back, lumbago, back pains, lack of vitality, poor appetite, atonic constipation, spastic constipation, paleness, anemia, and weak eyes, which were the conditions for which the article was offered in advertising sponsored by the distributor, Penn-Art Products.

DISPOSITION: March 12, 1954. Default decree of condemnation. The court ordered that the product be delivered to a local hospital.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4369. Adulteration and misbranding of Dexadex tablets. U. S. v. 437 Bottles * * *. (F. D. C. No. 36427. Sample No. 84339–L.)

LIBEL FILED: March 5, 1954, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 20, 1953, by Strong, Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 437 bottles of *Dexadex tablets* at Philadelphia, Pa. Analysis showed that the product contained 6.2 milligrams of dextro-amphetamine sulfate per tablet.

LABEL, IN PART: (Bottle) "Cabot 100 Tablets Dexadex * * * Each Tablet contains Dextro-Amphetamine Sulfate 10 mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 10 milligrams of dextro-amphetamine sulfate per tablet.

Misbranding, Section 502 (a), the label statement "Each Tablet contains Dextro-Amphetamine Sulfate 10 mg." was false and misleading as applied to a product containing less than the declared amount of dextro-amphetamine sulfate per tablet.

DISPOSITION: May 13, 1954. Default decree of condemnation. The court ordered that the product be delivered to a charitable institution.

4370. Adulteration of suprarenin tablets and procaine hydrochloride and epinephrine tablets. U. S. v. 12,473 Boxes, etc. (F. D. C. No. 36450. Sample Nos. 52638–L, 52639–L, 52641–L.)

LIBEL FILED: March 16, 1954, District of New Jersey.

ALLEGED SHIPMENT: During 1946, from various places outside the State of New Jersey.

PRODUCT: 12,473 boxes, each containing 5 vials, of *suprarenin tablets*, and 20,000 boxes, each containing 5 vials, and 6,300 boxes, each containing 10 vials, of *procaine hydrochloride and epinephrine tablets*, at Jersey City, N. J.

Analysis disclosed that the *suprarenin tablets* contained approximately 57.8 percent of the declared amount of epinephrine, and that the 20,000-box lot and the 6,300-box lot of the *procaine hydrochloride and epinephrine tablets* contained 75 percent and 52 percent, respectively, of the declared amount of epinephrine.

LABEL, IN PART: (Vial) "0.001 Gm. 20 Tablets * * * Suprarenin * * * Brand of Epinephrine (Synthetic) Each tablet contains Suprarenin Bitartrate 0.00182 Gm. equivalent to Suprarenin 0.001 Gm. (1/65 grain)," "20 Soluble Hypodermic Tablets Procaine Hydrochloride And Epinephrine Procaine Hydrochloride, 0.02 Gm.; Epinephrine 0.00005 Gm.," and "20 Tablets #20 Procaine HCl (USP) 1/3 Grain (0.02 Gm.) Epinephrine 1/1200 Grain (0.00005 Gm.)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strengths of the articles differed from that which they purported and were represented to possess since the article in the 12,473-box lot contained less than 0.001 gram (1/65 grain) of epinephrine per tablet; the article in the 20,000-box lot contained less than 0.00005 gram of epinephrine per tablet; and the article in the 6,300-box lot contained less than 1/1200 grain (0.00005 gram) of epinephrine per tablet. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: April 27, 1954. Default decree of condemnation and destruction.

4371. Adulteration of Special Formula ampuls. U. S. v. 1,141 Ampuls * * *. (F. D. C. No. 36226. Sample No. 82548–L.)

LIBEL FILED: January 4, 1954, Western District of New York.

ALLEGED SHIPMENT: On or about November 20, 1953, by the Vitamix Corp., from Philadelphia, Pa.

PRODUCT: 1,141 *Special Formula ampuls* at Rochester, N. Y.

LABEL, IN PART: "5 cc. Amps. Special Formula Each 5 cc. contains: Iron Cacodylate 0.03 gm. Emetine HCl 0.06 gm. In physiological salt solution * * * For Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since the article was represented as a drug suitable for intravenous use and it was not suitable for such use in that it was contaminated with viable micro-organisms and pyrogens.

DISPOSITION: February 12, 1954. Default decree of condemnation and destruction.

4372. Adulteration and misbranding of liver-folic acid-B_{12} and Foliver. U. S. v. 30 Vials, etc. (F. D. C. No. 36397. Sample Nos. 58616–L, 58617–L.)

LIBEL FILED: February 18, 1954, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about October 2 and 7, 1953, from Philadelphia, Pa.

PRODUCT: 30 vials of *liver-folic acid-B_{12}* and 41 vials of *Foliver* at Detroit, Mich. Analyses showed that the products contained less than 50 percent of the declared amount of vitamin B_{12}.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they purported and were represented to possess, namely, 60 micrograms of vitamin B_{12} per cubic centimeter.

Misbranding, Section 502 (a), the statement "Each cc. contains: Vit. B_{12} * * * 60 Mcg." appearing on the labels of the articles was false and misleading as applied to the articles, which contained less than 60 micrograms of vitamin B_{12} per cubic centimeter.

The articles were adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 16, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4373. Misbranding of C-Tone. U. S. v. 87 Bottles, etc. (F. D. C. No. 36158. Sample No. 26489–L.)

LIBEL FILED: December 3, 1953, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 22 and 30 and November 4, 1953, by Balanced Foods, Inc., from New York, N. Y.

PRODUCT: 87 8-ounce bottles of *C-Tone* at Philadelphia, Pa., together with a number of circulars entitled "Which of These Dread Killers Threaten Your Advancing Years?"

LABEL, IN PART: (Bottle) "Rich In Activated Enzymes C-Tone The Natural Vitamin C Tonic A splendid aid in quickly correcting conditions caused by deficiency of Vitamin C in the diet. This natural concentrate also supplies other essential nutritional factors as well as generous amounts of Pectin. Four tablespoons furnish: Natural Vitamin C 250 mg. Natural Rutin (Vitamin P Complex) 5 mg. Natural Vitamin K 1 mg. Natural Niacin 0.08 mg. Natural Pectin (Protopectins incl.) 500 mg. Natural Citric Acid 57 mg. Natural Chlorophyll 0.01 mg. and small amounts of natural Vitamin B_1 and B_2. Calcium and Phosphorus in a vegetable extract base rich in activated enzymes. * * * Sale and Exclusive Distributors Byrne Products, Inc. New York 7, N. Y."

*See also Nos. 4369, 4372.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Rich In Activated Enzymes" and "Vitamin C Tonic" were false and misleading since they represented and suggested that the article was of nutritional and therapeutic value because of enzyme content and was effective as a tonic, whereas the article was of no value because of its enzyme content and was not a tonic.

Further misbranding, Section 502 (a), certain statements in the above-mentioned circulars accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, and dizzy spells, and that the article was effective to provide energy and improve digestion. The article was not an adequate and effective treatment for such conditions, and it would not fulfill the promises of benefit stated and implied.

DISPOSITION: February 10, 1954. Default decree of condemnation and destruction.

4374. Misbranding of ACC capsules. U. S. v. 8 Cases, etc. (F. D. C. No. 36108. Sample No. 58598–L.)

LIBEL FILED: November 13, 1953, Northern District of Indiana.

ALLEGED SHIPMENT. On or about September 1 and October 5, 1953, from Baudette, Minn.

PRODUCT: 8 cases, each containing 100 bottles, of *ACC capsules* at Portland, Ind., in the possession of Alfalfa Concentrate, Inc., together with a number of leaflets designated "Announcing! ACC Alfalfa Capsules."

RESULTS OF INVESTIGATION: The above-mentioned leaflets were printed locally for the consignee and were distributed to wholesale drug firms along with the product for use by the drug firms' salesmen.

LABEL, IN PART: (Bottle) "One Hundred Capsules ACC Each Capsule Contains Active Ingredients: Salicylamide..... 3 grs. Inert Ingredients: Extract of Alfalfa..... 5 grs. Suggested Use As an aid in the relief of muscular aches and pains."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for the terrible pains of arthritis and rheumatism and that the alfalfa ingredient was active and contributed to the effectiveness of the article in such conditions. The article was not an adequate and effective treatment for the pains of arthritis and rheumatism, and the alfalfa ingredient was not active and did not contribute to the effectiveness of the article in such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 16, 1954. Default decree of condemnation and destruction.

4375. Misbranding of organic mineral salt. U. S. v. 6 Cases, etc. (F. D. C. No. 36115. Sample No. 54264–L.)

LIBEL FILED: November 12, 1953, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about August 20, 1953, by Dr. E. H. Bronner & Associates, from Los Angeles, Calif.

PRODUCT: 6 cases, each containing 24 6-ounce bottles, and 1 case, containing 24 12½-ounce bottles, of *organic mineral salt* at Detroit, Mich.

LABEL, IN PART: (Bottle) "Dr. Bronner's Organic-Mineral-Salt A Health Food Rich In Organically Grown Selected Vegetables, Minerals, Trace Elements, Iodine & Potash Contains dehydrated, uncooked, fine Alfalfa, Dulse, Okra, Vegetable-Seasoning, Wheat Germ, Soya, Parsley & over 6% of the 100% edible, 100% tooth-&-bone-building-Hereford-Texas-type Organic-Calcium-Phosphorous-Magnesium-Fluoride activated with high grade Brewers Yeast, Chlorophyll & Lecithin rich in all natural minerals & B-Complex Vitamins; Thiamin, Riboflavin, Niacin, B–12, Protein, Iron & Iodine."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "100% Dental-Decay-Prevention Proven * * * 1 ounce a day * * * guaranteed to prevent 100% tooth-decay * * * For proper elimination" were false and misleading since the article was not effective to prevent tooth decay and was not effective to insure proper elimination.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 20, 1954. Default decree of condemnation and destruction.

4376. Misbranding of Ru-Itis. U. S. v. 125 Bottles, etc. (F. D. C. No. 36107. Sample No. 73563–L.)

LIBEL FILED: November 7, 1953, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about August 5, 1953, by Whitney's Products, from Idaho Falls, Idaho.

PRODUCT: 125 bottles of *Ru-Itis* at Jersey Shore, Pa., together with a number of pamphlets entitled "Whitney's Ru-Itis Instructions" and "Whitney's Ru-Itis Arthritis Sufferers."

LABEL, IN PART: (Bottle) "Whitney's * * * Ru-Itis Useful for treatment of Arthritis Rheumatism and muscular aches and pains * * * A solution of Sulphur, Gly - cerine, Sulphurated Lime and Isopropyl Alcohol 6% 4 fluid ounces."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name of the article "Ru-Itis" and certain statements on the bottle label and in the above-mentioned pamphlets accompanying the article were false and misleading. The name and the statements represented and suggested that the article was an adequate and effective treatment for arthritis, rheumatism, and related conditions, whereas the article was not an adequate and effective treatment for arthritis, rheumatism, and related conditions.

DISPOSITION: March 4, 1954. Default decree of condemnation and destruction.

4377. Misbranding of Glycosol, Glycolator devices, and Glycosol with Chlorafal. U. S. v. 11 Devices, etc. (F. D. C. No. 36181. Sample Nos. 70011–L to 70013–L, incl.)

LIBEL FILED: December 16, 1953, District of Idaho.

ALLEGED SHIPMENT: On or about August 12 and September 2, 1953, by the Iron City Chemical Co., from Valencia, Pa.

PRODUCT: 11 *Rex Glycolator devices*, 10 *Royal Glycolator devices*, 7 *Furnace Glycolator devices*, and 5 *Monarch Glycolator devices*, and 13 cans of *Glycosol*

and 17 bottles of *Glycosol with Chlorafal* at Idaho Falls, Idaho, together with a number of leaflets designated "At Last!" "Guard Your Family," "Now We Can Prevent Colds," "There's A Glycolator For Every Home And Commercial Purpose," and "At Last * * * Germ Purified Air"; a number of pamphlets designated "What Glycolators Offer A Furnace Dealer"; a number of window streamers designated "Germ Warfare With The Glycolator" and "Germ-Free-Air Now Here"; and a brochure designated "Glycolator Division, Iron City Chemical Co. Valencia, Pa. Airborne Bacteria and Virus Control."

The *Glycolator devices* consisted of electrically heated receptacles for vaporizing triethylene glycol into the atmosphere of the room or other space served by the particular device.

LABEL, IN PART: (Can) "Glycosol Active Ingredient Triethylene Glycol 90% * * * Inert Ingredients 10% * * * Iron City Chemical Co. Valencia, Penna. Contents One U. S. Pint"; (bottle) "Glycosol Active Ingredient Triethylene Glycol 90% Inert Ingredients 10% * * * Chlorafal * * * Iron City Chemical Co. Valencia, Penna. Contents—One U. S. Pint."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets, window streamers, and brochures accompanying the devices and the drugs were false and misleading. The statements represented and suggested that the devices and the drugs in combination provided an adequate and effective treatment for preventing diseases due to airborne bacteria and virus, for preventing absenteeism in manufacturing plants and offices, and for preventing colds and other respiratory diseases, asthma, sinus conditions, mumps, and measles. The devices and the drugs in combination would not provide an adequate and effective treatment for such purposes.

DISPOSITION: January 26, 1954. Default decree of forfeiture. The court ordered that the devices, drugs, and printed matter be delivered to the Food and Drug Administration.

4378. Misbranding of Gyramatic mattress. U. S. v. 2 Mattresses, etc. (F. D. C. No. 36105. Sample No. 14742-L.)

LIBEL FILED: November 24, 1953, District of Wyoming.

ALLEGED SHIPMENT: On or about August 7, 1953, by the Gyramatic Co., from Denver, Colo.

PRODUCT: 2 *Gyramatic mattresses* at Casper, Wyo., together with a number of booklets designated "The Miracle Mattress Gyramatic It Relaxes You," a number of leaflets designated "Gyramatic for the Rest of your life!" and a display card designated "25¢ for 30 Minutes Was Your Trip Tiring?"

The *Gyramatic mattress* consisted of a coil spring mattress with a built-in motor attachment capable of causing an oscillating movement of the mattress.

LABEL, IN PART: "The Miracle Mattress Gyramatic * * * The Gyramatic Company—Denver, Colorado."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklets and leaflets and on the display card accompanying the mattresses were false and misleading. The statements represented and suggested that the mattresses were an adequate and effective treatment for circulatory ailments, arthritis, neuritis, insomnia, poor circulation, nervous tension, aches and pains, tired spine, fading vitality, tense nerves, taut muscles, paraplegia, nervous disorders, Parkinson's disease, traumatic cases, and headache. The mattresses were not an adequate and effective treatment for such conditions.

DISPOSITION: April 19, 1954. The consignee of the product having filed its acceptance of service and authorization to take a final decree, judgment of condemnation was entered and the court ordered that the product be sold at public auction to the highest bidder or turned over to a charitable institution.

DRUGS FOR VETERINARY USE

4379. Misbranding of Master Liquid. U. S. v. 19 Bottles * * * (and 3 other seizure actions). (F. D. C. Nos. 36140 to 36143, incl. Sample Nos. 84043–L to 84046–L, incl.)

LIBELS FILED: November 25 and 27, 1953, District of Minnesota.

ALLEGED SHIPMENT: On or about August 11, 13, 20, and 24, 1953, by Master Laboratories, Inc., from Omaha, Nebr.

PRODUCT: 114 1-gallon bottles and 4 5-gallon bottles of *Master Liquid* at Blue Earth, Truman, Springfield, and Windom, Minn.

LABEL, IN PART: (Bottle) "Master Liquid * * * Ingredients: Sodium Thio-Sulphate; Beechwood Creosote; Guaiacol; Powdered Extract of Licorice; Sodium Hydroxide 9%; Sodium Bicarbonate; Betanapthol; Oil of Anise; Sodium Phenosulfonate; Solution of Potassium Arsenite (Arsenic as Arsenous Oxide, 0.75%); Nicotinic Acid."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were misleading since they suggested and implied that the article was an effective remedy for diseases of swine, whereas it was not an effective remedy for such diseases: "Master Liquid For Old Hogs and Young Pigs * * * Estimate the largest amount of whole oats your hogs will eat in one day. For every three bushels of whole oats to be fed, mix 1 pint of Master Liquid * * * with 15 gallons of clean water * * * . To this solution add the whole oats and mix well by stirring. * * * Keep the prepared oats in feeding troughs at all times so hogs have free access to them. * * * Follow this practice for the first two weeks. The third week: Feed prepared oats in the morning and give other feeds during the remainder of the day. The fourth week: The animals can be put back on regular rations and thereafter fed prepared oats two or three days each week. On these days allow no other feed or they can be fed the preparation every morning and other feed the remainder of the day."

Further misbranding, Section 502 (a), the representation on the label "Alkalinizes Slops composed of Oats, Barley or Grain Mixtures" was misleading since the labeling of the article failed to reveal the material fact in the light of such representation that, whether or not the article alkalinized slops, such alkalinization was of no value or importance.

DISPOSITION: March 8, 1954. Default decrees of destruction.

4380. Misbranding of mineral feed. U. S. v. 56 Cartons * * *. (F. D. C. No. 36120. Sample No. 14741–L.)

LIBEL FILED: November 24, 1953, District of Wyoming.

ALLEGED SHIPMENT: On or about September 9, 1953, by the Mead Co., from Scottsbluff, Nebr.

PRODUCT: 56 cartons, each containing 1 50-pound block, of *mineral feed* at Sheridan, Wyo.

LABEL, IN PART: (Carton) "Mineral Worth-Mor Block Manufactured By Kay-Dee Feed Co. Sioux City, Iowa * * * Ingredients: Glauber's Salts (Sodium Sulfate), Baking Soda (Sodium Bicarbonate), Steamed Bone Meal,

Calcium Carbonate Sulfur, Copperas (Ferrous Sulfate), Cane Molasses, Iron Oxide, Magnesium Oxide, Potassium Iodide, Cobalt Sulfate, Copper Carbonate, Zinc Sulfate, Oil of Anise, Manganese Sulfate, D-Activated Plant Sterol (Source of Vitamin D–2), Methyl Polysiloxane (Anti-Foam Agent)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Contains Anti-Foam Agent Which Helps Prevent Bloat * * * New! Helps Prevent Bloat" were false and misleading since the article was not effective to prevent bloat in cattle and sheep.

DISPOSITION: March 3, 1954. The shipper of the product having authorized the entry of a final decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

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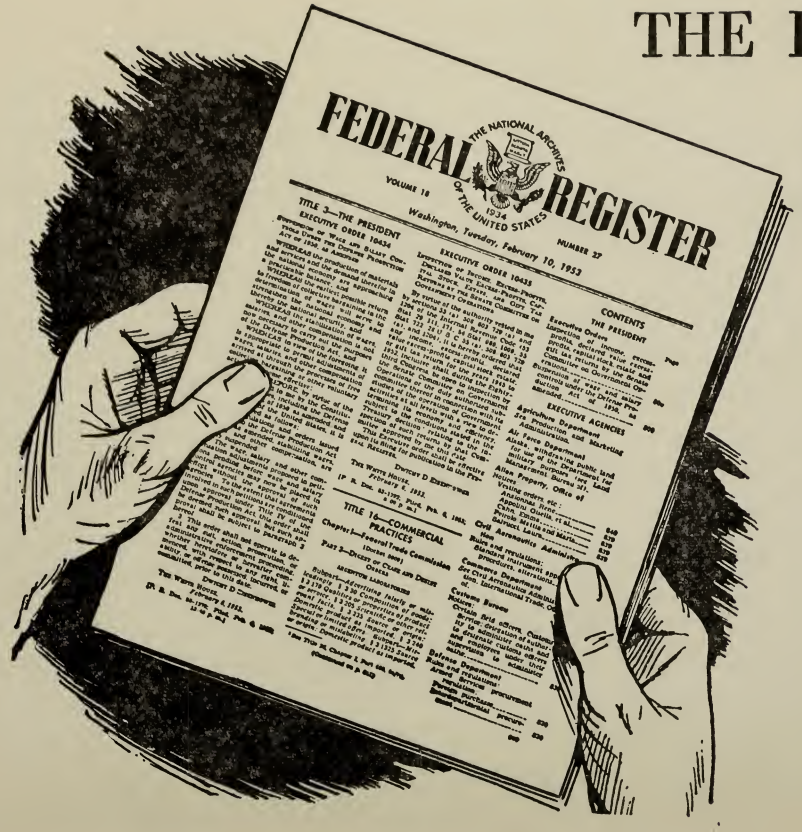

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D. D. N. J., F. D. C. 4381–4400 Issued June 1955

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4381–4400

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *June 2, 1955.*

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*For failure to comply with the packaging requirements of an official compendium, see No. 4394.

341366—55——1

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4381. Action to enjoin and restrain violations of Sections 301 (a) and 301 (k) with respect to Nu Youth tablets. U. S. v. Frederic S. Weichman, alias Fred Weichman, F. Weichman, and Fred Whiteman (N-Y Distributing Co.). Consent decree of injunction granted. (Inj. No. 277.)

COMPLAINT FILED: March 10, 1954, against Frederic S. Weichman, alias Fred Weichman, F. Weichman, and Fred Whiteman, doing business under the name of the N-Y Distributing Co., Hollywood, Calif.

NATURE OF CHARGE: The complaint alleged that the defendant was engaged in the interstate business of distributing and selling a drug consisting of 5 milligram methylandrostenediol tablets, designated by the name "Nu Youth"; that the methylandrostenediol contained in the *Nu Youth tablets* was believed to have been received in interstate commerce in the State of California, and that thereafter the defendant caused certain printed matter, including the label on the bottles containing the drug, a form letter addressed to "My Dear Friend," and a folder entitled "The Evidence," to become the labeling of the drug while held for sale after shipment in interstate commerce.

The complaint alleged further that the defendant was violating Section 301 (k) of the Act by causing the *Nu Youth tablets* to become misbranded while held for sale after shipment in interstate commerce, and that he also was violating Section 301 (a) of the Act by causing the introduction and delivery for introduction into interstate commerce of the misbranded *Nu Youth tablets*.

The *Nu Youth tablets* were alleged to be misbranded as follows:

Section 502 (a), the labeling of the tablets was false and misleading since it represented, suggested, and created the impression in the mind of the prospective purchaser to whom it was directed:

(a) That the tablets were an adequate and effective treatment for providing in men over 40 renewed vigor, endurance, strength, and vitality; for rejuvenating men by replenishing their deficient sex glands; for restoring masculine sex drive; for banishing mental fatigue, boosting muscle power, replenishing energy and endurance, increasing mental alertness, and ending irritability; for providing health, sexual aliveness, and emotional stability; for sex problems and impotency; for restoring waning physical and mental powers in men; for providing pep and vitality; and for providing proper functioning and well-being for the human body, whereas the tablets were not an adequate and effective treatment for such purposes and conditions;

(b) That the tablets may be used in place of the drugs, testosterone, methyltestosterone, and testosterone proprionate, for their androgenic effect, whereas the tablets possessed far less androgenic activity than those drugs;

(c) That each of the tablets was a natural, safe, needed, true, and normal male sex hormone, whereas each tablet was not a true or normal male sex hormone, nor was it a naturally occurring product, nor was it safe for use except under medical supervision, nor was it needed in normal body function; and,

(d) That each tablet was an anabolic agent, whereas the labeling failed to reveal the material fact in the light of such representation that

each tablet may not be safely used for such purposes without special dietary controls and specific therapy under medical supervision;

Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use;

Section 502 (f) (2), the labeling of the tablets failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, in such manner and form as are necessary for the protection of the user;

Section 502 (j), the tablets were dangerous to health when used in the dosage and with the frequency and duration recommended in the labeling. (The labeling suggested that the tablets be taken daily for a period up to 6 months in a dosage providing 10 milligrams of methylandrostenediol per day);

Section 503 (b) (1), the tablets, while being held for sale, were dispensed by the defendant without a prescription therefor from a practitioner licensed by law to administer the tablets; and,

Section 503 (b) (4), the tablets were subject to paragraph (1) of subsection (b) of Section 503 of the Act, and their label did not bear at all times prior to the dispensing of the tablets by the defendant the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: March 10, 1954. The defendant having consented to the entry of a decree, the court entered a decree of permanent injunction enjoining the defendant from the acts complained of.

VIOLATIVE SALES OF PRESCRIPTION DRUGS*

4382. Misbranding of amphetamine hydrochloride tablets. U. S. v. Clement S. Marczak (Polonia Pharmacy). Plea of not guilty. Tried to the court. Verdict of guilty. Fine of $2,000, plus costs, on counts 1 and 2 of information; imposition of fines on remaining 2 counts suspended. Sentence of 1 year in jail imposed on all counts and suspended. Defendant placed on probation for 2 years. (F. D. C. No. 34824. Sample Nos. 8897–L to 8900–L, incl.)

INFORMATION FILED: June 4, 1953, Northern District of Indiana, against Clement S. Marczak, trading as Polonia Pharmacy, Hammond, Ind.

NATURE OF CHARGE: On or about July 27 and August 3, 7, and 27, 1952, while a number of *amphetamine hydrochloride tablets* were being held for sale at the Polonia Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: The defendant having entered a plea of not guilty, the case came on for trial before the court without a jury on January 29, 1954; and, at the conclusion of the trial on the same day, the court rendered a verdict of guilty. On May 7, 1954, the court fined the defendant $1,000, plus costs, on each of counts 1 and 2 and suspended the imposition of fines on the remaining 2 counts of the information. The court also imposed a jail sentence of 1 year on all counts, but suspended this sentence and placed the defendant on probation for 2 years.

*See also No. 4381.

4383. Misbranding of triple sulfa tablets, pentobarbital sodium capsules, amphetamine sulfate tablets, and a quantity of chloral hydrate. U. S. v. Herbert Thompson (Closson & Kelly Drug Store). Plea of guilty. Sentence of 1 year in jail and fine of $2,000. (F. D. C. No. 35163. Sample Nos. 64091–L, 64096–L, 64098–L, 64101–L, 64106–L.)

INFORMATION FILED: September 8, 1953, Western District of Washington, against Herbert Thompson, trading as Closson & Kelly Drug Store, Seattle, Wash.

NATURE OF CHARGE: On or about February 19 and March 10, 13, 18, and 19, 1953, while a number of *triple sulfa tablets, pentobarbital sodium capsules, amphetamine sulfate tablets*, and a quantity of *chloral hydrate* were being held for sale at the Closson & Kelly Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: May 13, 1954. The defendant having entered a plea of guilty, the court imposed a sentence of 1 year in jail and a fine of $2,000.

4384. Misbranding of methantheline bromide tablets, methamphetamine hydrochloride tablets, and tablets containing a mixture of phenobarbital, hyoscyamine sulfate, atropine sulfate, and hyoscine hydrobromide. U. S. v. Cecil Haggard (the Corner Drug Store), and Harold D. Frankel. Pleas of guilty. Fine of $400 against Defendant Haggard and $100 against Defendant Frankel, plus costs. (F. D. C. No. 35189. Sample Nos. 56980–L, 71052–L, 71059–L, 71062–L, 71073–L.)

INFORMATION FILED: October 21, 1953, Eastern District of Kentucky, against Cecil Haggard, trading as the Corner Drug Store, Winchester, Ky., and Harold D. Frankel, a pharmacist.

NATURE OF CHARGE: On or about April 27 and June 1, 3, and 5, 1953, while a number of *methantheline bromide tablets, methamphetamine hydrochloride tablets*, and *tablets containing a mixture of phenobarbital, hyoscyamine sulfate, atropine sulfate, and hyoscine hydrobromide* were being held for sale at the Corner Drug Store, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Defendant Haggard was charged with causing the acts of dispensing involved in each of the 5 counts of the information, and Defendant Frankel was joined as a defendant in count 4. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: May 25, 1954. Defendant Haggard having entered a plea of guilty to 4 of the 5 counts of the information and Defendant Frankel having entered a plea of guilty to count 4, the court fined Defendant Haggard $400 and Defendant Frankel $100, plus costs.

4385. Misbranding of methylparafynol capsules, secobarbital sodium capsules, and capsules containing a mixture of secobarbital sodium and amobarbital sodium. U. S. v. John M. Minarsini (Western Drugs). Plea of nolo contendere. Fine of $250, plus costs. (F. D. C. No. 35766. Sample Nos. 33586–L, 33602–L to 33604–L, incl., 65717–L.)

INFORMATION FILED: January 19, 1954, Northern District of Illinois, against John M. Minarsini, trading as Western Drugs, Chicago, Ill.

NATURE OF CHARGE: On or about June 2, 11, 12, 16, and 30, 1953, while a number of *methylparafynol capsules, secobarbital sodium capsules,* and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were being held for sale at Western Drugs, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: February 15, 1954. The defendant having entered a plea of nolo contendere, the court fined him $250, plus costs.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

4386. Misbranding of whole pituitary capsules and anterior pituitary tablets. U. S. v. 279 Bottles, etc. (F. D. C. No. 36455. Sample Nos. 52127–L, 52130–L, 52162–L, 52163–L.)

LIBEL FILED: March 18, 1954, Southern District of New York.

ALLEGED SHIPMENT: On or about December 29, 1953, and January 19, 1954, by Armour Laboratories, from Bradley, Ill.

PRODUCT: 279 bottles of *whole pituitary capsules* and 36 bottles of *anterior pituitary tablets* at New York, N. Y.

LABEL, IN PART: (Bottle) "100 – 1 Grain (60 mg.) List 3100 Whole Pituitary Capsules Each Capsule Contains 1 Grain (60 mg.) Of Whole Calf Pituitary Powder Caution: Federal law prohibits dispensing without prescription. Directions For Use Will Be Supplied To Physicians Upon Request * * * The Armour Laboratories A Division Of Armour And Company, Chicago, Illinois" and "Armour 100 – 5 Grain Anterior Pituitary Tablets Each Tablet Contains 5 Grains Anterior Pituitary * * * Caution: To be dispensed only by or on the prescription of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use.

Further misbranding, Section 503 (b) (4), the articles were drugs to which Section 503 (b) (1) did not apply, and the labels of the drugs, prior to dispensing, bore a caution against dispensing the drugs without a prescription.

DISPOSITION: April 22, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

4387. Misbranding of anterior pituitary injectable and whole ovarian injectable. U. S. v. 44 Vials, etc. (F. D. C. No. 36442. Sample Nos. 40022–L, 40023–L.)

LIBEL FILED: March 18, 1954, Southern District of California.

ALLEGED SHIPMENT: On or about October 6 and November 13, 1953, by the Difco Laboratories, from Detroit, Mich.

PRODUCT: 44 vials of *anterior pituitary injectable* and 71 vials of *whole ovarian injectable* at Glendale, Calif., in possession of the Nelson Pharmacal Co.

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*See also No. 4381.
**See also Nos. 4381, 4386.

RESULTS OF INVESTIGATION: The consignee relabeled the products after their shipment in interstate commerce.

LABEL, IN PART: (Vial) "Nelson 30 cc. Anterior Pituitary Injectable * * * List No. 270 * * * Each cc. contains the water soluble heat stable, extractives derived from (18½ gr.) 1.2 Gm. fresh anterior pituitary lobes. * * * Preservative: Chlorobutanol (chloroform derivative) 0.5%" and "Nelson 30 cc. Whole Ovarian Injectable * * * List No. 280 * * * Each cc. contains the water soluble heat stable, extractives derived from 40 gr. of fresh whole ovarian tissue. Preservative: Chlorobutanol (chloroform derivative) 0.5%."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use. The articles were misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: April 8, 1954. Default decree of condemnation and destruction.

4388. Misbranding of ultrasonic device. U. S. v. 1 Device, etc. (F. D. C. No. 34464. Sample No. 40623–L.)

LIBEL FILED: January 15, 1953, Western District of Washington.

ALLEGED SHIPMENT: On or about June 5, 1952, by R. J. Lindquist, from Los Angeles, Calif.

PRODUCT: 1 *ultrasonic device* at Seattle, Wash., together with 1 copy of a two-page translation from Pohlmon "Die Ultraschalltherapie," 1 copy of an instruction booklet designated "Lindquist 'Chronosonic' Ultrasound Generator Model 401," and 1 copy of printed matter designated "Bulletin * * * Ultrasonics In Therapy."

The above-mentioned instruction booklet indicated that the device would give off ultrasonic energy at approximately 1 megacycle frequency and at a maximum energy intensity output of 2 watts per square centimeter of "head."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned translation and in the above-mentioned bulletin accompanying the device were false and misleading. The statements represented and suggested that the device would provide an adequate and effective treatment for abscesses, adnexitis, angina pectoris, arthritis, asthma, Bechterew's disease, bed-wetting, bronchitis (bronchiectasis), bursitis, causalgia, colecystitis, colesystopathic, coccygodynia, colitis, coxarthrosis, diphtheric bacilli carriers, glands (tumefaction), Dupuytren's contracture, dysbasia, elephantiasis, eczema, endangitis obliterans, epicondylitis, epilepsy, erythema nodosa, erythromelalgia, fistula, furuncle, carbuncle, joint effusion, gingivitis, urethral stricture, skin carcinoma, hemiplegia, herpes zoster, hypertonia essential, infiltrations, intercoastal neuralgia, induratio penis plast, ischialgia, lockjaw, lumbago, lymphadenitis, mastitis, Meniere's disease, multiple sclerosis, myalgia, myelitis, scar contraction, neuralgia, neuritis, neuroma after amputation, osteomyelitis, ostitis, periostitis, panaris, paradentosis, parotitis, paronychia, parulis, periarthritis, phlegmon, polyarthritis, postoperative pain, prostatitis, pruritus, pulpitis, Raynaud's disease, rheumatism, X-ray ulcers, scalenus syndrom, sweat glands abscess, scleroderma, sinusitis, spondylosis, sudek'sche dystrophy, tendovaginitis, thrombophlebitis, tonsillitis, trigeminus neuralgia, tuberculosis, tumors, ulcus cruris, gastrointestinal ulcers, warts, dental granuloma, cellulitis, radiculitis, kieferhoehlenentzuendung, and nebenhoehlenentzuendung. The device would not provide an adequate and effective treatment for such conditions.

Further misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: Robert V. Carroll appeared as claimant and filed an answer denying that the device was misbranded. On May 25, 1954, the claimant having represented to the court that he was no longer interested in the device under seizure and believed no useful purpose would be served by contesting the case, and also having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the device be destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4389. Adulteration of German chamomile. U. S. v. 115 Packages * * *. (F. D. C. No. 36224. Sample No. 57095–L.)

LIBEL FILED: January 4, 1954, Northern District of Ohio.

ALLEGED SHIPMENT: On or about November 12, 1953, by the Rexall Drug Co., from Pittsburgh, Pa.

PRODUCT: 115 packages of *German chamomile* at Cleveland, Ohio.

LABEL, IN PART: "1 Ounce Rexall U (Various Numbers) Puretest German Chamomile Matricaria Chamomilla, Lin."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects, insect parts, and rodent hairs.

DISPOSITION: March 12, 1954. Default decree of condemnation and destruction.

4390. Adulteration and misbranding of herb tea. U. S. v. 57 Bags, etc. (F. D. C. No. 36222. Sample No. 58896–L.)

LIBEL FILED: January 13, 1954, Northern District of Illinois.

ALLEGED SHIPMENT: On or about April 21 and 22, 1942, from Jersey City, N. J.

PRODUCT: 57 bags and 140 boxes of *herb tea* at Chicago, Ill., in possession of the Z. G. Stanis Co., together with a number of leaflets entitled "Temporary List Of Z. G. Herbs And Stanis Products."

RESULTS OF INVESTIGATION: The product contained in the bags represented a portion of a bulk shipment of 217 bags, and the product in the boxes had been repackaged by the consignee from the bulk shipment. The above-mentioned leaflets were printed locally for the consignee.

LABEL, IN PART: (Bag) "102 Lbs. Seventeana Tea"; (box) "Z – G Herbs * * * Net Weight 4 Oz. No. 17 * * * Herb Tea Seventeen is a composition of select herbs, barks, roots, flowers and seeds, intended to promote and help maintain regular elimination * * * List of ingredients * * * Burdock Root Boneset Herb Catnip Herb Centuary Herb Comfrey Root Condurango Bark Echinacea Root Fennel Seed Horsetail Rush Lemon Balm Life Root Herb Pipsissewa Herb Sarsaparilla Root Saffron Flowers Sassafras Bark Senna Pods Senna Leaves Uva Ursi Leaves Wormwood Herb Yarrow Herb."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects, insect parts, and rodent excreta; and, Section 501 (a) (2), the article had been held under insanitary conditions whereby it may have been and had been contaminated with filth by reason of its exposure to attack by insects and rodents.

Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for stomach disorders, whereas the article was not an adequate and effective treatment for stomach disorders.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 13, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4391. Adulteration and misbranding of phenobarbital tablets, Pyraphen tablets, and Luasmin capsules. U. S. v. Brewer & Co., Inc., and Howard D. Brewer. Pleas of guilty. Fine of $1,200 against corporation and $300 against individual. (F. D. C. No. 35565. Sample Nos. 33768–L, 44871–L, 45078–L.)

INFORMATION FILED: March 2, 1954, District of Massachusetts, against Brewer & Co., Inc., Worcester, Mass., and Howard D. Brewer, president and treasurer of the corporation.

ALLEGED SHIPMENT: On or about January 29, February 23, and March 6, 1953, from the State of Massachusetts into the States of Connecticut, Illinois, and New Hampshire.

LABEL, IN PART: (Bottle) "10,000 Phenobarbital Tablets U. S. P. (1½ gr.) 0.1 Gm. Brewer & Company, Inc. Worcester, Mass.," "100 Tablets Pyraphen–Therland—Each tablet contains: Pyrilamine Maleate (¾ gr.) 50 mg. Aminophylline (3 gr.) 0.2 Gm. Phenobarbital (¼ gr.) 15 mg. Therland Drug Co. 20 Farmington Avenue Hartford, Conn. Distributors," and "100 Capsules Luasmin Each capsule contains: Theophylline Sodium Acetate (3 gr.) 0.2 Gm. Ephedrine Sulfate (½ gr.) 30 mg. Phenobarbital Sodium (½ gr.) 30 mg. Brewer & Company, Inc. Worcester, Mass., U. S. A."

NATURE OF CHARGE: *Phenobarbital tablets.* Adulteration, Section 501 (d) (2), a substance, namely, phenobarbital sodium tablets, had been substituted for *phenobarbital tablets.* Misbranding, Section 502 (a), the label statement "Phenobarbital Tablets" was false and misleading since the article did not consist of *phenobarbital tablets* but consisted of another substance, namely, phenobarbital sodium tablets.

Pyraphen tablets. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet purported and was represented to contain (3 grains) 0.2 gram of aminophylline, whereas each tablet contained less than that amount of aminophylline. Misbranding, Section 502 (a), the label statement "Each tablet contains: * * * Aminophylline (3 gr.) 0.2 Gm." was false and misleading.

Luasmin capsules. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each capsule of the article purported and was represented to contain (½ grain) 30 milligrams of phenobarbital sodium, whereas each capsule contained more than that amount of phenobarbital sodium. Misbranding, Section 502 (a), the label statement "Each capsule contains: * * * Phenobarbital Sodium (½ gr.) 30 mg." was false and misleading.

DISPOSITION: May 6, 1954. The defendants having entered pleas of guilty, the court fined the corporation $1,200 and the individual $300.

4392. Adulteration and misbranding of Eprinal. U. S. v. 270 Bottles, etc. (F. D. C. No. 36326. Sample Nos. 30949–L, 30950–L.)

LIBEL FILED: February 19, 1954, Eastern District of Missouri.

ALLEGED SHIPMENT: Sometime prior to January 1, 1951, from Chicago, Ill.

PRODUCT: 270 15-cc. bottles and 150 30-cc. bottles of *Eprinal* at St. Louis, Mo. Analysis showed that the product, which was represented as "Epinephrine Inhalation," contained 0.5 gram of epinephrine in each 100 cc., whereas the United States Pharmacopeia provides that "Epinephrine Inhalation" contains not less than 0.9 gram of epinephrine in each 100 cc.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Epinephrine Inhalation," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard set forth in such compendium.

Misbranding, Section 502 (a), the label designation "Epinephrine Inhalation U. S. P." and the label statement "Each 100 cc. contains Epinephrine 1 Gram" were false and misleading as applied to an article which contained 0.5 gram of epinephrine per 100 cc.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 25, 1954. Default decree of condemnation and destruction.

4393. Adulteration and misbranding of Special Formula tablets. U. S. v. 44,725 Tablets * * *. (F. D. C. No. 36492. Sample No. 51024–L.)

LIBEL FILED: April 21, 1954, Eastern District of New York.

ALLEGED SHIPMENT: On or about August 25, 1953, from Newark, N. J.

PRODUCT: 44,725 *Special Formula tablets* in 1 drum at Long Island City, N. Y. Analysis showed that the product contained 50 percent of the declared amount of vitamin D.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 134 U. S. P. units of vitamin D per tablet.

Misbranding, Section 502 (a), the label statement "Each tablet contains: * * * 134 U. S. P. Units Vitamin D" was false and misleading as applied to a product which contained less than 134 U. S. P. units of vitamin D per tablet.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 20, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4394. Misbranding of procaine hydrochloride ampuls. U. S. v. 19 Crates * * *. (F. D. C. No. 36457. Sample No. 48010–L.)

LIBEL FILED: March 23, 1954, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about November 5, 1947, from Savannah, Ga.

*See also Nos. 4381, 4388, 4390–4393.

PRODUCT: *Procaine hydrochloride ampuls.* 19 crates, each containing 325 boxes and each box containing 10 ampuls, at New Orleans, La. Visual examination of the ampuls disclosed that in 33 ampuls out of 60 examined, crystals of the material were sticking to the walls of the ampul and could not be dislodged. Thus, when the top of the ampul was filed off, varying percentages of the procaine hydrochloride would be lost.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Each Ampule Contains: Sterile Procaine HCl 120 mgm." was false and misleading as applied to the article since, when opened and used in the customary manner, a portion of the procaine hydrochloride would adhere to the necks of the ampuls and the quantity delivered would be substantially less than 120 milligrams.

Further misbranding, Section 502 (g), the article purported to be "Sterile Procaine Hydrochloride," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the article was not labeled as prescribed therein since the lot number was not stated on the label of each container.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 5, 1954. Default decree of condemnation and destruction.

4395. Misbranding of apple juice concentrate and chlorophyll formula. U. S. v. 83 Bottles, etc. (F. D. C. No. 36168. Sample Nos. 62671–L, 62672–L.)

LIBEL FILED: December 2, 1953, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about July 15, 1953, by El Rancho Adolphus Products, Inc., from Scranton, Pa.

PRODUCT: 83 1-quart bottles of *apple juice concentrate* and 10 16-ounce bottles and 10 8-ounce bottles of *chlorophyll formula* at St. Louis, Mo., together with a number of leaflets designated "Adolphus Hohensee Gall Stone And Kidney Stone Diet No. 5" and a number of booklets designated "Chlorophyll Therapy By Dr. T. M. Rudolph, Ph. D."

LABEL, IN PART: (Bottle) "El Rancho Adolphus Brand Pure Apple Juice Concentrate Made from Selected Apples Dilute with water, 4 parts to 1 of concentrate. * * * Distributed by * * * El Rancho Adolphus Products, Inc. Hohensee Park, Jermyn, Pa." and "El Rancho Adolphus * * * Chlorophyll Formula Highly purified water-soluble chlorophyll (Sodium Magnesium Chlorophyllin). Concentration 0.2 percent in saline (sodium chloride) solution."

NATURE OF CHARGE: *Apple juice concentrate.* Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was effective in the treatment of gallstones and kidney stones. The article was not effective in the treatment of such conditions.

Chlorophyll formula. Misbranding, Section 502 (a), certain statements in the above-mentioned booklets accompanying the article were false and misleading. The statements represented and suggested that the article was effective in the treatment of high blood pressure, anemia, disturbances of the stomach and intestinal lining, oral infections, chronic osteomyelitis, varicose ulcers, sinusitis, hay fever, rhinitis, otitis media, otitis externa, Vincent's angina, pyorrhea, gingivitis, tonsillitis, laryngitis, pharyngitis, peptic ulcer, gastritis, enteritis, colitis, vaginitis, trichomonas vaginalis, leucorrhea,

cervical ulcer, diseases of the urinary bladder, pruritus ani, hemorrhoids, hardening of the arteries, and arthritis. The article was not effective in the treatment of such conditions.

DISPOSITION: February 10, 1954. Nutrition Center, Inc., St. Louis, Mo., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the bottles of *apple juice concentrate* and *chlorophyll formula* be released to the claimant for the purpose of selling such articles and that the leaflets and the booklets be held by the Department of Health, Education, and Welfare.

The decree provided also that the *apple juice concentrate* and the *chlorophyll formula* should not be sold with any other leaflets or booklets identical to, or similar to, those which were seized; and that none of the products should be disposed of by the claimant until the Department of Health, Education, and Welfare, or the United States attorney, should have had further access thereto in order to take any samples or make any tests deemed necessary and have released such products for sale or other disposition.

4396. Misbranding of Hercules Tonic Tea No. 5 and Hercules Regulator Laxative and Diuretic Tea. U. S. v. 207 Packages, etc. (F. D. C. No. 36366. Sample Nos. 71766–L, 71767–L.)

LIBEL FILED: January 29, 1954, Northern District of Indiana.

ALLEGED SHIPMENT: On or about October 21, 1953, from Jersey City, N. J.

PRODUCT: 207 packages of *Hercules Tonic Tea No. 5* and 201 packages of *Hercules Regulator Laxative and Diuretic Tea* at Michigan City, Ind., in possession of the Hercules Tea Co., together with a number of booklets entitled "Read And Save This Valuable Booklet Hercules Tea Co."

RESULTS OF INVESTIGATION: The shipment described above was a bulk shipment, and upon its receipt by the consignee, was repackaged and relabeled. The above-mentioned booklets were printed for the consignee and were distributed to customers and prospective customers.

LABEL, IN PART: (Package) "Hercules Tonic Tea No. 5 * * * 3 Ozs. * * * Formula Linden Flowers Chamomile Juniper Fennel Pale Rose Buds Elder Flowers Senna * * * Best Investment For Your Health It may do wonder for you—make you feel, eat, sleep, work and enjoy better life" and "Hercules Regulator Laxative and Diuretic Tea 3 Ozs. * * * Formula: — Elder, Anise, Fennel, Chamomile, Rose Buds, and Senna. Acts as a laxative and to increase the flow of Urine."

NATURE OF CHARGE: *Hercules Tonic Tea No. 5.* Misbranding, Section 502 (a), certain statements on the label of the article and in the above-mentioned booklet accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for enabling one to feel, eat, sleep, work, and enjoy better life; and for invalidism, rundown condition, providing internal health, strengthening the system, unbalanced nerves, impaired digestion, unbalanced nervous temperament, impaired condition of physical energy, restoring red blood cells, sluggish kidneys, backache, dizziness, headache, loss of pep, nervousness, rheumatic pains, providing an antiseptic to the urine, and preventing anemia, nervous breakdown, rheumatism, liver and kidney troubles, ulcers, Bright's disease, diabetes, and gallstones. The article was not an adequate and effective treatment for such conditions and purposes.

Hercules Regulator Laxative and Diuretic Tea. Misbranding, Section 502 (a), certain statements on the label of the article and in the above-mentioned booklet accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for biliousness, loss of appetite, sleeplessness, headache, dizziness, and torpidity, and for preventing anemia, nervous breakdown, rheumatism, liver and kidney troubles, ulcers, Bright's disease, diabetes, and gallstones. The article would not be an adequate and effective treatment for such conditions and purposes.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: March 12, 1954. Default decree of condemnation and destruction.

4397. Misbranding of Special Herb Formula and Wildunger Brand herb tea. U. S. v. 2 Drums, etc. (F. D. C. No. 36367. Sample Nos. 54293–L to 54296–L, incl.)

LIBEL FILED: February 2, 1954, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about August 3 and October 22, 1953, from Jersey City, N. J.

PRODUCT: 2 100-pound drums, 1 90-pound drum, and 4 pounds of *Special Herb Formula*, and 18 cartons of the *Special Herb Formula* repackaged from the bulk drums under the name of *Wildunger Brand herb tea* at Detroit, Mich., in possession of the Botanical Mail-Order House, together with a number of loose labels for application to the cartons as repacked; a number of empty cellophane envelopes labeled, in part, "Sample Trial Size (Makes One Quart) Wildunger Brand Herb Tea A Stimulant Diuretic," which envelopes were for use in distributing free samples of the product; a number of form letters identified as "Dear Friend: At your request," "Dear Friend: At the request of one of your," "Dear Friend: Your order for Wildunger," "Dear Friend: Some time ago we mailed you a sample of our famous Wildunger Brand Herb Tea," and "Gentlemen: Please accept with our compliments"; a number of leaflets identified as "Gutchten Werte Herren," "Gutachten Liebe Freunde," "This Is It," and "Wildunger Brand Herb Tea Is Here At Last"; and a number of folders entitled "Wildunger Brand Herb Tea A Stimulant Diuretic."

RESULTS OF INVESTIGATION: The repackaging of the product was done by the consignee. Some of the above-mentioned form letters, leaflets, and folders were printed locally for the consignee, and some were mimeographed by the consignee at his place of business.

LABEL, IN PART: (Drum) "Cut & Sifted Hoffmann's Special Herb Formula #141 Revised"; (carton) "Wildunger Brand Herb Tea A Stimulant Diuretic Wildunger 'Brand' Herb Tea is prepared by a special process and contains the following ingredients: Bean Shells, Corn Silk, Birch Leaves, Bearberry Leaves, Shave Grass, Buchu Leaves, Licorice Root, Anise Seed, Peppermint Leaves. 6½ Oz. Approx. Weight * * * Prepared For and Distributed By Botanical Mail-Order House Detroit 19, Michigan."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the above-mentioned carton labels, cellophane envelopes, form letters, leaflets, and folders accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for metabolic disorders, kidney disorders, bladder disorders, conditions which manifest themselves by abnormal urine, excessive thirst,

hunger, or fatigue, nervousness, rheumatism, urinary disorders, swelling of the ankles, gout, diabetes, gallstones, liver trouble, bed wetting, colds, bronchial congestion, and chills. The article was not an adequate and effective treatment for such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 14, 1954. Default decree of condemnation and destruction.

4398. Misbranding of C-Tone. U. S. v. 13 Bottles, etc. (F. D. C. No. 36470. Sample No. 46084–L.)

LIBEL FILED: March 30, 1954, District of Rhode Island.

ALLEGED SHIPMENT: The product was shipped on or about January 13 and February 24, 1954, by Balanced Foods, Inc., from New York, N. Y., and a number of circulars were shipped on or about September 13, 1953, from Thrush Press, Inc., from New York, N. Y.

PRODUCT: 13 bottles of *C-Tone* at Providence, R. I., together with a number of circulars entitled "Which Of These Dread Killers Threaten Your Advancing Years?"

LABEL, IN PART: (Bottle) "C-Tone The Natural Vitamin C Tonic A splendid aid in quickly correcting conditions caused by deficiency of Vitamin C in the diet. This natural concentrate also supplies other essential nutritional factors as well as generous amounts of Pectin. Four tablespoons furnish: Natural Vitamin C 250 mg. 8 MDR Natural Rutin (Vitamin P Complex) 5 mg.* Natural Vitamin K 1 mg.* Natural Niacin 0.08 mg.** Natural Pectin (Protopectins incl.) 500 mg.* Natural Citric Acid 57 mg.* Natural Chlorophyll 0.01 mg.* and small amount of natural Vitamin B_1 and B_2, Calcium and Phosphorous in a vegetable extract base rich in activated enzymes.

MDR—Minimum Daily Requirement
*Need in human nutrition not established
**Minimum Daily Requirement not established

8 Fl. Oz. Net * * * Sale and Exclusive Distributors Byrne Products, Inc. New York 7, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the bottle label "Vitamin C Tonic" and "rich in activated enzymes" were false and misleading since they represented and suggested that the article was of nutritional and therapeutic value because of its enzyme content and that it was effective as a tonic, whereas the article was of no value because of its enzyme content and was not a tonic.

Further misbranding, Section 502 (a), certain statements in the above-mentioned circular accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, and dizzy spells, and that it was effective to provide energy and improve digestion. The article was not an adequate and effective treatment for such conditions, and it was not capable of fulfilling the promise of benefit made for it.

DISPOSITON: April 28, 1954. Default decree of condemnation. The court ordered that the product be delivered to a State institution and that the circulars be destroyed.

4399. Misbranding of chlorine and hydrogen device. U. S. v. 2 Devices, etc. (F. D. C. No. 36475. Sample Nos. 82326–L, 82327–L.)

LIBEL FILED: April 1, 1954, Western District of Oklahoma.

ALLEGED SHIPMENT: On or about March 20, 1948, by Rittenhouse & Revere, Inc., from Albuquerque, N. Mex.

PRODUCT: 2 *chlorine and hydrogen devices* at Oklahoma City, Okla., in possession of Dr. Charles H. McDonald, D. C., together with one copy of a booklet designated "Nascent Haloid Vapor * * * Treatment," one copy of a booklet designated "Diseases of the Nasal Accessory Sinuses," and one copy of a booklet designated "Catalog * * * Generator * * * Nascent Haloid Vapor * * * Rittenhouse & Revere, Inc.," a number of leaflets designated "Factors of Importance in the Treatment of Sinusitis," and a number of form letters designated "Dear Friend."

The device was assumed to be one for electrolyzing salt (sodium chloride) solution, and for producing hydrogen gas and chlorine gas, which were blown out of the device by means of a small electric fan through a delivery tube for administration to the patient.

RESULTS OF INVESTIGATION: The above-mentioned booklets were received by the consignee from the shipper of the product, and the leaflets and form letters were printed locally for use by the consignee to induce prospective patients to come to the consignee's office for treatment with the device.

LABEL, IN PART: (Nameplate) "Controlled E. M. F. Electro Chemical Analytic and Electrolytic Generator * * * Rittenhouse & Revere, Inc. Albuquerque, New Mexico."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklets, leaflets, and form letters accompanying the device were false and misleading. The statements represented and suggested that the device provided an adequate and effective treatment for sinus infections, respiratory diseases, rheumatoid arthritis, internal disease, acute and chronic rhinitis, bronchitis, catarrh, inflammation of the nose, chronic head cold, nose trouble, permanent nose infection, tonsillitis, laryngitis, asthma, and lung abscess, and for preventing kidney disease, gallbladder disease, urine bladder infections, ear disease, and meningitis. The device would not provide an adequate and effective treatment for such conditions and purposes. The device was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: May 5, 1954. Default decree of condemnation. The court ordered that the devices under seizure, together with the booklets, leaflets, and letters, be delivered to the Food and Drug Administration.

4400. Misbranding of Vibra-Life Massage Chair. U. S. v. 7 Devices, etc. (F. D. C. No. 35389. Sample No. 73423–L.)

LIBEL FILED: August 18, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about March 21, 1953, from Morristown, Tenn.

PRODUCT: 7 devices designated as *Vibra-Life Massage Chairs* at Atlantic City, N. J., in possession of the Vibra-Life Chair Co., together with a number of pamphlets entitled "Vibra-Life Vibrating Mechanical Massage Chairs" and a number of placards entitled "Vibra-Life Chair Co.," "Good Circulation is Good Health," "It vibrates for health & comfort," and "Relax In Comfort In A Vibra-Life Chair."

Examination showed that the chairs were of two types. One chair was a leisure lounge type, which rocked to the position of the body and then was locked into position. The other was a regular easy chair, but adjusted automatically with the motion of the body to any position, from sitting to reclining, without knobs or levers. Both types were equipped with a 1/50 hp. motor. A switch on the side of the chair started the motor, which would vibrate the chair for as long as desirable. The vibration would stop when the switch was turned off.

RESULTS OF INVESTIGATION: The above-mentioned pamphlets were printed for the consignee and distributed to prospective customers, while the above-mentioned placards were on display at the consignee's place of business.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned pamphlets and placards accompanying the device were false and misleading. The statements represented and suggested that the device provided an adequate and effective treatment for circulatory disorders, sore muscles, aches and pains, arthritis, rheumatism, varicose veins, asthma, neuritis, aching back, and sciatica, and that it would insure good health. The device would not provide an adequate and effective treatment for such conditions. The device was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 6, 1954. Default decree of condemnation. The court ordered that one complete chair be delivered to the Food and Drug Administration, together with a number of the pamphlets and one of the placards; that the remaining chairs be delivered to a charitable institution, after the motors and any nameplates and other identification marks had been removed; and that the motors so removed be delivered to another charitable organization.

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SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

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[1] (4382) Prosecution contested.
[2] (4381) Injunction issued.

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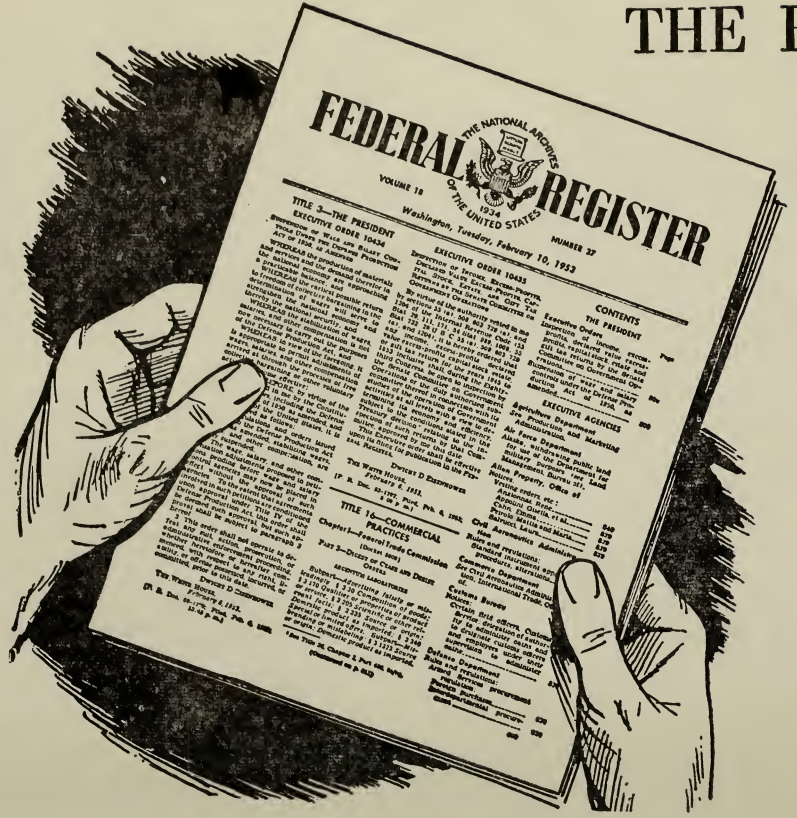

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4401–4420

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *July 20, 1955.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

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INFORMATION FILED: April 14, 1954, Northern District of Illinois, against the Claridge Pharmacy, a partnership, Chicago, Ill., and Lester Weitzman, a partner and pharmacist in the partnership.

NATURE OF CHARGE: On or about June 4, 11, 21, and 30, 1953, while a number of *methylparafynol capsules* and *methyltestosterone tablets* were being held for sale at the Claridge Pharmacy, after shipment in interstate commerce, the defendants caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: May 10, 1954. The defendants having entered pleas of guilty, the court fined the partnership $100, plus costs, and the individual $300.

4402. Misbranding of methyltestosterone tablets and methantheline bromide tablets. U. S. v. Cecil E. Brown and Payton J. Powers. Pleas of guilty. Each defendant fined $500 and sentenced to 3 months in jail. Jail sentence suspended and defendants placed on probation for 18 months. (F. D. C. No. 35770. Sample Nos. 69143–L, 69242–L, 69243–L, 69247–L.)

INFORMATION FILED: January 5, 1954, Northern District of Texas, against Cecil E. Brown and Payton J. Powers, pharmacists at the West Pharmacy, Plainview, Tex.

NATURE OF CHARGE: On or about June 13, 15, 20, and 29, 1953, while a number of *methyltestosterone tablets* and *methantheline bromide tablets* were being held for sale at the West Pharmacy, after shipment in interstate commerce, the defendants caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: May 4, 1954. The defendants having entered pleas of guilty, the court fined each defendant $500 and sentenced each to 3 months in jail. The jail sentence was suspended, and the defendants were placed on probation for 18 months.

4403. Misbranding of methantheline bromide tablets, penicillin G crystalline potassium tablets, and a quantity of paraldehyde. U. S. v. Mark Begley and Eugene H. Hager. Pleas of guilty. Fine of $100 against Eugene H. Hager and $200 against Mark Begley, plus costs. (F. D. C. No. 35791. Sample Nos. 56982–L, 71053–L, 71055–L.)

INFORMATION FILED: February 26, 1954, Eastern District of Kentucky, against Mark Begley, a partner in the partnership of Begley Drug, Hazard, Ky., and against Eugene H. Hager, pharmacist for the partnership.

NATURE OF CHARGE: On or about April 28 and June 3, 1953, while a number of *methantheline bromide tablets, penicillin G crystalline potassium tablets,* and a quantity of *paraldehyde* were being held for sale at Begley Drug, after shipment

in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Eugene H. Hager was charged with causing the dispensing of the *paraldehyde* and Mark Begley was charged with causing the dispensing of the other drugs involved. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: May 10, 1954. Pleas of guilty having been entered, the court fined Mark Begley $200 and Eugene H. Hager $100, plus costs.

4404. Misbranding of methantheline bromide tablets, penicillin G potassium tablets, thyroid tablets, and diethylstilbestrol tablets. U. S. v. David W. McGuire (McGuire Pharmacy), and James T. Gilkey, Sr. Pleas of guilty. Fine of $400 against Defendant McGuire and $100 against Defendant Gilkey, plus costs. (F. D. C. No. 35753. Sample Nos. 71057–L, 71061–L, 71065–L, 71069–L, 71072–L.)

INFORMATION FILED: January 20, 1954, Eastern District of Kentucky, against David W. McGuire, trading as McGuire Pharmacy, Winchester, Ky., and James T. Gilkey, Sr., a pharmacist.

NATURE OF CHARGE: On or about June 3, 5, and 8, 1953, while a number of *methantheline bromide tablets*, *penicillin G potassium tablets*, *thyroid tablets*, and *diethylstilbestrol tablets* were being held for sale at McGuire Pharmacy, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Defendant McGuire was charged with causing the acts of dispensing involved in each of the five counts of the information and Defendant Gilkey was joined as a defendant in three of the counts. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: May 25, 1954. Defendant McGuire having entered a plea of guilty to 4 counts of the information and Defendant Gilkey having entered a plea of guilty to count 3, the court imposed a fine of $400 against Defendant McGuire and a fine of $100 against Defendant Gilkey, plus costs.

4405. Misbranding of penicillin G crystalline potassium tablets, troches containing, among other things, dextro-amphetamine phosphate, thyroid tablets, and diethylstilbestrol tablets. U. S. v. Henry H. Horton. Plea of guilty. Fine of $400, plus costs. (F. D. C. No. 35758. Sample Nos. 56976–L, 71066–L, 71068–L, 71074–L.)

INFORMATION FILED: January 20, 1954, Eastern District of Kentucky, against Henry H. Horton, an employee of the George Drug Store, Winchester, Ky.

NATURE OF CHARGE: On or about April 27 and June 5 and 8, 1953, while a number of *penicillin G crystalline potassium tablets*, *troches containing, among other things, dextro-amphetamine phosphate*, *thyroid tablets*, and *diethylstilbestrol tablets* were being held for sale at the George Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: May 24, 1954. The defendant having entered a plea of guilty, the court fined him $400, plus costs.

4406. Misbranding of methamphetamine hydrochloride tablets and thyroid tablets. U. S. v. Charles W. Atwell. Plea of guilty. Fine, $75. (F. D. C. No. 35777. Sample Nos. 56893–L, 57050–L, 57072–L.)

INFORMATION FILED: April 1, 1954, Northern District of Ohio, against Charles W. Atwell, a pharmacist for Stein's Pharmacy, Akron, Ohio.

NATURE OF CHARGE: On or about March 12 and 31 and June 1, 1953, while a number of *methamphetamine hydrochloride tablets* and *thyroid tablets* were being held for sale at Stein's Pharmacy, after shipment in interstate commerce, Defendant Atwell caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: April 19, 1954. The defendant having entered a plea of guilty, the court fined him $75.

4407. Misbranding of methamphetamine hydrochloride tablets, diphenhydramine hydrochloride capsules, and phenylbutazone tablets. U. S. v. Arthur L. Gates (Gates' Professional Pharmany). Plea of guilty. Fine, $50. (F. D. C. No. 35797. Sample Nos. 45105–L, 45106–L, 45536–L, 45538–L, 45592–L, 45594–L.)

INFORMATION FILED: March 17, 1954, District of Vermont, against Arthur L. Gates, trading as Gates' Professional Pharmacy, Burlington, Vt.

NATURE OF CHARGE: On or about July 20, 27, 28, and 31, and August 3, 1953, while a number of *methamphetamine hydrochloride tablets*, *diphenhydramine hydrochloride capsules*, and *phenylbutazone tablets* were being held for sale at Gates' Professional Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed upon requests for refills of written prescriptions therefor without obtaining authorization by the prescriber. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: March 30, 1954. The defendant having entered a plea of guilty, the court fined him $50.

4408. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Oscar Sussman (Sussman's Drugs), and Samuel H. Lubinsky. Pleas of guilty. Each defendant fined $100. (F. D. C. No. 35748. Sample Nos. 51864–L, 51869–L.)

INFORMATION FILED: March 17, 1954, District of New Jersey, against Oscar Sussman, trading as Sussman's Drugs, Paterson, N. J., and Samuel H. Lubinsky, a pharmacist.

NATURE OF CHARGE: On or about April 6 and 28, 1953, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at Sussman's Drugs, after shipment in interstate commerce, various quantities of the drug were dispensed without a prescription from a practitioner licensed by law to administer such drug. Defendant Sussman was charged with causing the acts of dispensing involved in each of the two counts of the information, and Defendant Lubinsky was joined as a defendant in one of the counts. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: May 10, 1954. The defendants having entered pleas of guilty, the court fined each defendant $100.

4409. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Henry D. Schmauch (Peoples Drug Store). Plea of guilty. Fine, $50. (F. D. C. No. 35778. Sample Nos. 35512–L, 64956–L, 64958–L.)

INFORMATION FILED: March 10, 1954, Western District of Wisconsin, against Henry D. Schmauch, trading as the Peoples Drug Store, La Crosse, Wis.

NATURE OF CHARGE: On or about August 10 and 11, 1953, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at the Peoples Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drug to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: March 30, 1954. The defendant having entered a plea of guilty, the court fined him $50.

4410. Misbranding of phenobarbital tablets, sulfathiazole tablets, and amphetamine sulfate tablets. U. S. v. Robert C. Prather (Central Drug Store). Plea of guilty. Fine, $100. (F. D. C. No. 34822. Sample Nos. 46293–L, 46295–L, 46296–L, 46298–L.)

INFORMATION FILED: February 4, 1954, Middle District of Alabama, against Robert C. Prather, trading as the Central Drug Store, Phenix City, Ala.

NATURE OF CHARGE: On or about July 23, 24, and 25, 1952, while a number of *phenobarbital tablets*, *sulfathiazole tablets*, and *amphetamine sulfate tablets* were being held for sale at the Central Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: April 5, 1954. The defendant having entered a plea of guilty, the court imposed a fine of $100.

4411. Misbranding of probarbital calcium tablets, secobarbital sodium capsules, and lozenges containing a mixture of penicillin, bacitracin, sulfadiazine, and benzocaine. U. S. v. Cecil V. Good (Summersville Pharmacy). Plea of guilty. Fine, $500. (F. D. C. No. 35795. Sample Nos. 53707–L, 53709–L, 63212–L.)

INFORMATION FILED: March 25, 1954, Western District of Missouri, against Cecil V. Good, trading as Summersville Pharmacy, Summersville, Mo.

NATURE OF CHARGE: On or about October 8 and 27, 1953, while a number of *probarbital calcium tablets*, *secobarbital sodium capsules*, and *lozenges containing a mixture of penicillin, bacitracin, sulfadiazine, and benzocaine* were being held for sale at Summersville Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: April 1, 1954. The defendant having entered a plea of guilty, the court fined him $500.

4412. Misbranding of phenylbutazone tablets, chloramphenicol capsules, and conjugated estrogens tablets. U. S. v. Donahoe Pharmacy, Inc., and Victor Goldman. Pleas of guilty. Fine of $150 against corporation and $50 against individual. (F. D. C. No. 35763. Sample Nos. 45150–L, 45531–L, 45532–L, 45557–L to 45559–L, incl.)

INFORMATION FILED: February 2, 1954, District of Massachusetts, against Donahoe Pharmacy, Inc., Natick, Mass., and Victor Goldman, president of the corporation.

NATURE OF CHARGE: On or about June 24 and July 1, 6, and 13, 1953, while a number of *phenylbutazone tablets*, *chloramphenicol capsules*, and *conjugated estrogens tablets* were being held for sale at Donahoe Pharmacy, Inc., after shipment in interstate commerce, the defendants caused a number of the *phenylbutazone tablets* and *chloramphenicol capsules* to be dispensed upon requests for refills of written prescriptions without obtaining authorization by the prescribers and caused a number of *conjugated estrogens tablets* to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: March 26, 1954. The defendants having entered pleas of guilty, the court fined the corporation $150 and the individual $50.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4413. Misbranding of Special Formula tablets. U. S. v. 1 Drum, etc. (F. D. C. No. 36491. Sample No. 51025–L.)

LIBEL FILED: April 20, 1954, Eastern District of New York.

ALLEGED SHIPMENT: On or about December 24, 1953, by Faraday Laboratories, from Newark, N. J.

PRODUCT: *Special Formula tablets.* 1 drum containing 25,000 red-coated tablets and 1 drum containing 25,000 green-coated tablets at Long Island City, N. Y., in possession of Edward J. Moore Sons, together with a number of loose labels intended for use in repackaging the tablets.

LABEL, IN PART: (Drum) "Spec. Formula S. C. Red (or Green) Each tablet contains: Quinine HCL. 2½ gr. Dried Ferrous Sulfate 1 gr. Ext. Black Haw Bk. Tree 1 gr. Ext. Wild Yam Root 1 gr. Jamaica Ginger ½ gr. Aloin 1/11 gr. Caution: Federal law prohibits dispensing without prescription. * * * Bulk Shipment For Repackaging and Relabeling Only."; (loose labels) "Red Sanger Number 5 (or Green Corbin No. 10) Contains: Dried Ferrous Sulfate (Iron 20 mgs.), Quinine Hydrochloride, Aloin, P. E. Wild Yam, P. E. Black Haw, and Ginger. For the relief of pains not due to organic disease ordinarily associated with the menstrual period. Dose: Adults only, 2 capsules before each meal (6 capsules per day) during menstruation. * * * Contains 24 Capsules Distributed by Sanger & Company (or Corbin Capsule Company) 10–93 Jackson Ave., Long Island City 1, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use since their labeling did not bear a statement of the recommended or usual dose, nor information as to the use of the drug by practitioners licensed by law to administer such drug; and such information was not contained in scientific literature. The tablets were misbranded in such respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the labeling of the tablets, namely, the label designated "Red Sanger Number 5" intended for use in repackaging the red-coated tablets and the label designated "Green Corbin No. 10" intended for use in repackaging the green-coated tablets, contained statements which represented and suggested that the tablets (red-coated and green-coated tablets) were efficacious in the relief of pain not due to organic disease ordinarily associated with the menstrual period. Such statements were false and misleading since the tablets were not efficacious in the relief of pain not due to organic disease ordinarily associated with the menstrual period. The tablets were misbranded in such respect while held for sale after shipment in interstate commerce.

DISPOSITION: May 20, 1954. Default decree of condemnation and destruction.

4414. Misbranding of Devine's Zina-Ray oil and Devine's inhaler. U. S. v. 432 Bottles, etc. (F. D. C. No. 36472. Sample Nos. 61106–L, 61107–L.)

LIBEL FILED: On or about April 1, 1954, Western District of Missouri.

ALLEGED SHIPMENT: On or about December 23, 1953, and February 5, 1954, from Chicago, Ill.

PRODUCT: 720 1-ounce bottles and 4 cartons, each carton containing 12 dozen 3-ounce bottles, of *Devine's Zina-Ray oil*, and 40 boxes, each containing 200 *Devine's inhalers*, at Kansas City, Mo., in possession of Susan Buckhinder.

RESULTS OF INVESTIGATION: The articles were promoted for sale through demonstrations given by Mrs. Buckhinder, a representative of Devine's Remedies, Inc., Chicago, Ill. During the course of these demonstrations, Mrs. Buckhinder would recommend the articles for use in the treatment and prevention of various diseases and conditions.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in the treatment of sinus, migraine headaches, arthritis, neuritis, lumbago, and asthma, and for preventing tonsillitis, laryngitis, bronchitis, and pneumonia, which were the conditions and purposes for which the articles were intended. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 24, 1954. Default decree of forfeiture and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4415. Adulteration and misbranding of liver injection. U. S. v. Bio-Ramo Drug Co., Inc., and Dr. Clifford W. Price. Pleas of not guilty. Tried to the court. Verdict of guilty against corporation; motion granted for dismissal of charge against individual. Fine of $750, plus costs, against corporation. (F. D. C. No. 35557. Sample No. 26462–L.)

INFORMATION FILED: January 6, 1954, District of Maryland, against Bio-Ramo Drug Co., Inc., Baltimore, Md., and Dr. Clifford W. Price, technical director of the corporation.

ALLEGED SHIPMENT: On or about February 26, 1953, from the State of Maryland into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Liver Injection Crude," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since each cubic centimeter of the

article had a vitamin B_{12} activity equivalent to less than 2 micrograms of cyanocobalamin, the minimum permitted by the standard.

Misbranding, Section 502 (a), the label statements "Liver Injection, Crude, U. S. P. Each cc has a Vitamin B–12 activity equivalent to 2 micrograms of cyanocobalamin" were false and misleading. The statements represented and suggested that the article conformed to the specifications of the United States Pharmacopeia for "Liver Injection Crude," and that the vitamin B_{12} activity of the article was equivalent to 2 micrograms of cyanocobalamin per cubic centimeter. The article did not conform to the specifications of the United States Pharmacopeia for "Liver Injection Crude," and the vitamin B_{12} activity of the article was not equivalent to 2 micrograms of cyanocobalamin per cubic centimeter.

DISPOSITION: May 4, 1954. The defendants having entered pleas of not guilty, the case came on for trial before the court without a jury. At the conclusion of the testimony, the court granted the defendants' motion for dismissal of the charge against Dr. Price and returned a verdict of guilty against the corporation. The corporation was fined $750, plus costs.

4416. Adulteration of compound bismuth subgallate tablets. U. S. v. 3,500 Tablets * * *. (F. D. C. No. 36687. Sample No. 63476–L.)

LIBEL FILED: March 17, 1954, Southern District of Illinois.

ALLEGED SHIPMENT: On or about September 10, 1953, by Wilson-Keith & Co., from St. Louis, Mo.

PRODUCT: 3,500 tablets in a bulk container at Elmwood, Ill. Analysis showed that the article contained more than the declared quantity of copper arsenite.

LABEL, IN PART: "Compressed Tablets Each Tablet Contains: Copper Arsenite—1/200 Gr."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1/200 grain of copper arsenite.

DISPOSITION: April 9, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4417. Action to enjoin and restrain the interstate shipment of "No-Fast." U. S. v. "No-Fast" Mfg. & Distributing Co. Default decree of permanent injunction granted. (Inj. No. 269.)

COMPLAINT FILED: March 9, 1954, District of Colorado, against the "No-Fast" Mfg. & Distributing Co., a corporation, Denver, Colo.

NATURE OF CHARGE: That the defendant had been and was at the time of the filing of the complaint, introducing and causing to be introduced, into interstate commerce, a drug called "*No-Fast*" which consisted of petroleum jelly, magnesium trisilicate, magnesium oxide, sodium bicarbonate, bismuth subnitrate, sodium chloride, and honey, and which was misbranded as follows:

Section 502 (a), certain statements on the label of the article and in a leaflet enclosed with the article were false and misleading since the statements represented that the article was effective for the relief of stomach irritations, stomach ulcers, constipation, gastritis, acid indigestion, and hemorrhoids, whereas the article was not so effective.

*See also Nos. 4413, 4415.

DISPOSITION: On April 7, 1954, a preliminary injunction was entered against the defendant; and, on May 6, 1954, a default decree was entered perpetually enjoining the defendant from directly or indirectly, introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, the above-described drug called "*No-Fast*" or any similar drug which was misbranded under Section 502 (a). The decree specifically provided that the misbranding prohibited by the injunction applied to any such drug, the labeling of which was false and misleading in any particular, or which represented or suggested that such drug was beneficial, effective, or had any value in the cure, mitigation, or treatment of the diseases and conditions named above. The use as labeling of a leaflet headed "Diet and Care Suggestions," a round yellow label entitled "No-Fast," and a yellow carton entitled "No-Fast" also was particularly prohibited by the decree.

4418. Misbranding of Duodex capsules. U. S. v. 36 Cartoned Bottles * * *. (F. D. C. No. 36441. Sample No. 45963–L.)

LIBEL FILED: March 11, 1954, District of Massachusetts.

ALLEGED SHIPMENT: On or about October 23, 1953, and January 21, 1954, by Harris Laboratories, Inc., from Glen Cove, N. Y.

PRODUCT: 36 cartoned bottles of *Duodex capsules* at Boston, Mass.

LABEL, IN PART: (Carton) "100 Capsules * * * Duodex * * * Each capsule contains approximately 0.3 grams of desiccated and partially defatted duodenal substance."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article, namely, (carton label) "for Relief of Stomach Ulcer Pains * * * to relieve ulcer pains and symptoms of ulcerative colitis * * * for indigestion * * * gastritis," (bottle label) "for acid indigestion," and (display carton) "New Effective Relief For Ulcer Sufferers * * * Contains duodenal substance—the new discovery you read about * * * Contains scientifically prepared duodenal substance you read about it in the * * * "American Weekly," were false and misleading. The article would not relieve ulcer pains and the symptoms of ulcerative colitis, was not effective in the treatment of gastritis and indigestion, was not a new effective relief for ulcer sufferers, and was not an adequate and effective treatment for healing and preventing peptic ulcer, ulcerative colitis, and duodenal ulcer, which were the purposes for which duodenal substance was recommended in the December 5, 1948, issue of the "American Weekly," referred to in the Duodex labeling.

DISPOSITION: May 17, 1954. Default decree of condemnation and destruction.

4419. Misbranding of mineral dietary supplement, Lanocel, and mineral bath. U. S. v. 19 Bottles, etc. (F. D. C. No. 36169. Sample Nos. 64726–L to 64728–L, incl.)

LIBEL FILED: January 6, 1954, Western District of Washington.

ALLEGED SHIPMENT: On or about September 20 and October 2 and 6, 1953, by Tique Revive, from Los Angeles and Pasadena, Calif.

PRODUCT: 19 bottles of *mineral dietary supplement*, 18 jars of *Lanocel*, and 131 boxes of *mineral bath* at Seattle, Wash., together with a number of booklets entitled "Tique Revive 3 point plan for health & beauty"; a number of leaflets entitled "Natures Perfect Internal Cosmetic," "Tique Revive Health & Beauty Thru Natural Minerals," and "Help Yourself To Nature's Way of Intestinal

Health"; and a number of mimeographed sheets entitled "Tique Revive offers an unparalleled opportunity to women who have sales ability."

LABEL, IN PART: (Bottle) "En beaute mineral dietary supplement Each days' supply of 6 tablets furnish: Calcium (gluconate and phosphate) . . . 750 mgm. 100% Phosphorus (dibasic calcium phosphate) . . . 450 mgm. 60% Iron (ferrous gluconate) . . . 22 mgm. 220% Iodine (Kelp) . . . 0.2 mgm. 200% Formulated in a natural Namin base. Directions: 2 tablets after each meal * * * Net contents 100 Tablets"; (jar) "Lanocel by Tique Revive 22 * * * Each ounce of Lanocel Contains 10,000 International Units of Vitamin D & Lanolin * * * Net Weight 8 Oz."; (box) "Sea And Sand mineral baths with Tingle Tub by Tique Revive * * * net contents 2 lbs. 13 oz."

NATURE OF CHARGE: *Mineral dietary supplement.* Misbranding, Section 502 (a), certain statements in the above-mentioned booklets, leaflets, and mimeographed sheets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for constipation, intestinal gas, bloating, intestinal distress, irritated intestinal tract, internal disorders, that tired worn-out feeling, abnormal functioning of the nervous system, poor disposition, loss of appetite, retarded growth, disturbance of the reproductive functions, impure blood, kidney disorders, underweight, nervousness, skin disorders, obesity, impotence, low vitality, frigidity, skin disease, troublesome skin conditions, acne, blemishes, and enlarged pores; for providing good blood, ambition, normal blood vessels, normal functioning of the nervous system, proper growth, and normal functioning of the blood, thyroid, and spleen; for building the brain and nervous system; for stimulating growth of hair; for normalizing the digestive tract; and for providing vibrant health and natural beauty. The article was not an adequate and effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it.

Lanocel. Misbranding, Section 502 (a), certain statements on the jar label, in the leaflets entitled "Tique Revive Health & Beauty Thru Natural Minerals," and in the above-mentioned mimeographed sheets and booklets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for wrinkles, blemishes, blackheads, whiteheads, oily pores, enlarged pores, brittle nails, skin infections, acne, and severe burns. The article was not an adequate and effective treatment for such conditions.

Mineral bath. Misbranding, Section 502 (a), certain statements on the label of the article, in the leaflets entitled "Tique Revive Health & Beauty Thru Natural Minerals," and in the above-mentioned mimeographed sheets and booklets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for fatigue, tension, muscular aches and pains, aching feet, nervous tension, troublesome skin conditions, acne, blemishes, enlarged pores, arthritis, neuritis, and painful condition of the limbs; for providing a vibrant clear skin condition; and for stimulating the circulation and adding firmness and tone to the overall body. The article was not an adequate and effective treatment for such conditions and purposes.

DISPOSITION: May 19, 1954. Default decree of condemnation and destruction.

4420. Misbranding of C-Tone. U. S. v. 16 Bottles, etc. (F. D. C. No. 36480. Sample No. 40417-L.)

LIBEL FILED: April 5, 1954, Southern District of California.

ALLEGED SHIPMENT: On or about October 8, 1953, by Byrne Products, Inc., from New York, N. Y.

PRODUCT: 16 bottles of *C–Tone* at San Diego, Calif, together with a number of circulars entitled "Which Of These Dread Killers Threaten Your Advancing Years?"

LABEL, IN PART: (Bottle) "Rich In Activated Enzymes C–Tone The Natural Vitamin C Tonic A splendid aid in quickly correcting conditions caused by deficiency of Vitamin C in the diet. This natural concentrate also supplies other essential nutritional factors as well as generous amounts of Pectin. Four tablespoons furnish: Natural Vitamin C. . . . 250 mg. 8 MDR Natural Rutin (Vitamin P Complex). . . . 5 mg.* Natural Vitamin K. . . . 1 mg.* Natural Niacin. . . . 0.08 mg.** Natural Pectin (Protopectins incl.). . . . 500 mg.* Natural Citric Acid. . . . 57 mg.* Natural Chlorophyll . . . 0.01 mg.* and small amounts of natural Vitamin B_1 and B_2, Calcium and Phosphorous in a vegetable extract base rich in activated enzymes.

MDR—Minimum Daily Requirement
*Need in human nutrition not established
**Minimum Daily Requirement not established

8 Fl. Oz. Net * * * Sale and Exclusive Distributors Byrne Products, Inc. New York 7, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Rich In Activated Enzymes" and "Vitamin C Tonic" were false and misleading since they represented and suggested that the article was of nutritional and therapeutic value because of enzyme content and that it was effective as a tonic, whereas the article was of no value because of its enzyme content and was not a tonic.

Further misbranding, Section 502 (a), certain statements on the above-mentioned circular accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, and dizzy spells, and that it was effective to provide energy and improve digestion. The article was not an adequate and effective treatment for such conditions, and it was not capable of fulfilling the promise of benefit made for it.

DISPOSITION: May 18, 1954. Default decree of condemnation and destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4415) Prosecution contested.
[2] (4417) Injunction issued.

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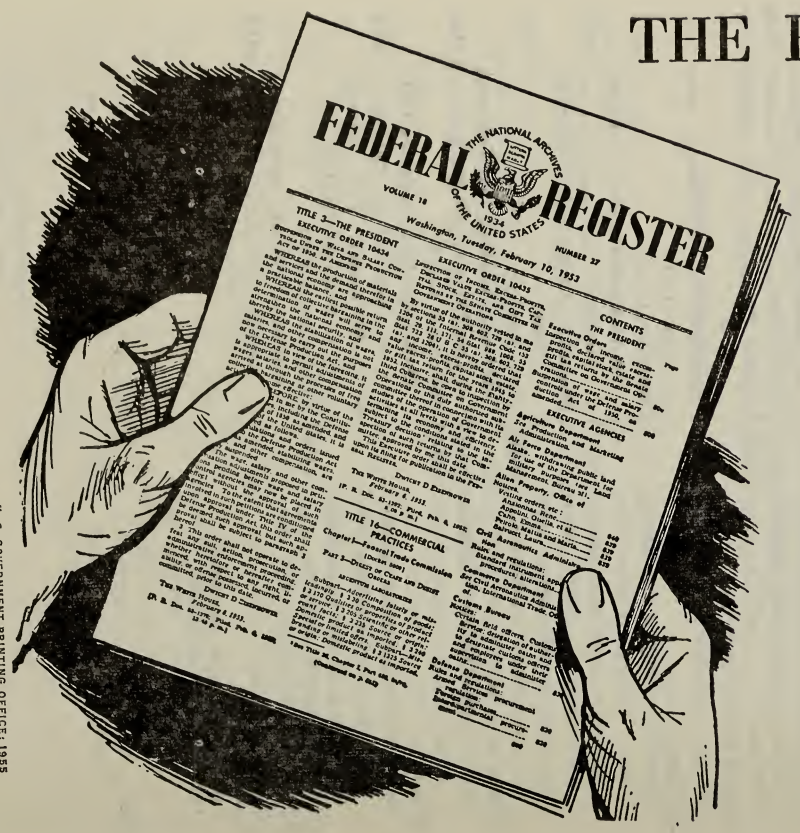
[2] (4417) Injunction issued.

THE FEDERAL REGISTER



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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4421–4440

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *August 15, 1955.*

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NEW DRUG SHIPPED WITHOUT EFFECTIVE A[redacted]

4421. Enverm syrup. U. S. v. 120 Cartoned Bottles * * *. (F. D. C. No. 36551. Sample No. 75369–L.)

LIBEL FILED: On or about May 5, 1954, District of Maryland.

ALLEGED SHIPMENT: On or about April 2, 1954, by the Manhattan Drug Co., from Brooklyn, N. Y.

PRODUCT: 120 cartoned bottles of *Enverm syrup* at Baltimore, Md.

LABEL, IN PART: (Carton and bottles) "Enverm Syrup For Pinworms Preservatives, Sodium Benzoate 0.1%, Methylparaben 0.1%. Each CC contains the equivalent of 100 mg. Piperazine Hexahydrate * * * 2 Fl. Ozs."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: June 2, 1954. Default decree of condemnation and destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4422. Misbranding of penicillin G potassium tablets. U. S. v. 9 Bottles * * *. (F. D. C. No. 36791. Sample No. 49667–L.)

LIBEL FILED: May 17, 1954, Eastern District of New York.

ALLEGED SHIPMENT: On or about March 1, 1954, by Morse Laboratories, Inc., from Hoboken, N. J.

PRODUCT: 9 100-tablet bottles of *penicillin G potassium tablets* in 1 carton at Brooklyn, N. Y.

LABEL, IN PART: (Carton) "Buffered Penicillin Tablets Crystalline G Potassium 200,000 units * * * Lot 3754 Expiration Date Feb."

NATURE OF CHARGE: Misbranding, Section 502 (l), the article purported to be and was represented as a drug composed in whole or in part of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law.

DISPOSITION: June 22, 1954. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE

4423. Adulteration and misbranding of Bact-A-Cin ointment. U. S. v. 120 Tubes * * *. (F. D. C. No. 36819. Sample No. 46091–L.)

LIBEL FILED: June 2, 1954, District of New Jersey.

ALLEGED SHIPMENT: On or about May 13, 1954, from Fall River, Mass. This was a return shipment.

PRODUCT: 120 tubes of *Bact-A-Cin ointment* at Newark, N. J. Analysis showed that the product contained less than 85 percent of the declared penicillin potency.

LABEL, IN PART: (Tube) "One-Dose Rockland Bact-A-Cin Procaine Penicillin G and Dihydrostreptomycin with Bacitracin Ointment for the treatment of

[redacted] Veterinary Use Only Contains Procaine Penicillin G . . . . 300,000 units Dihydrostreptomycin (as sulfate) . . . . 50 mg. Bacitracin . . . . 5,000 units In a suitable Ointment Base * * * Lot No. 1 Exp. Date March 1955."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (l), the article purported to be and was represented as a drug composed in whole or in part of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law.

DISPOSITION: September 21, 1954. Default decree of condemnation and destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4424. Misbranding of secobarbital sodium capsules, amphetamine sulfate tablets, methyltestosterone tablets, and capsules containing a mixture of secobarbital sodium and amobarbital sodium. U. S. v. James E. Neels. Plea of guilty. Fine $400. (F. D. C. No. 35789. Sample Nos. 62439–L, 62440–L, 63045–L, 63046–L.)

INFORMATION FILED: March 1, 1954, Eastern District of Missouri, against James E. Neels, a pharmacist for Neels Drugs, St. Louis, Mo.

NATURE OF CHARGE: On or about August 31, September 17, and October 8, 1953, while a number of *secobarbital sodium capsules, amphetamine sulfate tablets, methyltestosterone tablets,* and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were being held for sale at Neels Drugs, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed upon requests for refills of written prescriptions therefor without obtaining authorization by the prescriber. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: March 12, 1954. The defendant having entered a plea of guilty, the court fined him $400.

4425. Misbranding of pentobarbital sodium capsules. U. S. v. Jack I. Lipson. Plea of nolo contendere. Fine, $300. (F. D. C. No. 35119. Sample Nos. 62245–L, 62246–L.)

INFORMATION FILED: March 16, 1954, Eastern District of Arkansas, against Jack I. Lipson, a pharmacist for the Owl Drug Store, West Memphis, Ark.

NATURE OF CHARGE: On or about October 12 and 20, 1952, while a number of pentobarbital sodium capsules were being held for sale at the Owl Drug Store, after shipment in interstate commerce, the defendant caused a number of capsules of the drug to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: March 16, 1954. The defendant having entered a plea of nolo contendere, the court fined him $300.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4426. Misbranding of suprarenal concentrate capsules and yellow bone marrow concentrate. U. S. v. 213 Bottles, etc. (F. D. C. No. 36512. Sample Nos. 37528–L, 37529–L.)

LIBEL FILED: April 20, 1954, District of New Jersey.

ALLEGED SHIPMENT: On or about December 2, 1953, and January 20 and February 16, 1954, by the Armour Laboratories, from Bradley, Ill.

PRODUCT: 213 bottles of *suprarenal concentrate capsules* and 90 bottles of *yellow bone marrow concentrate* at East Paterson, N. J.

LABEL, IN PART: (Bottle) "100—2 Grain Suprarenal Concentrate Capsules Each Capsule Contains The Powdered Concentrate Derived From 15 Grains Of Fresh Suprarenal Glands Relatively Free From Epinephrine. The Armour Laboratories * * * Chicago 11, Ill." and "Armour Laboratories 100 Glanules Y. B. M. Yellow Bone Marrow Concentrate * * * Indications: Mild Chronic Agranulocytosis Due To Infection Or The Toxic Action Of Drugs * * * Each Glanule Contains 21 Milligrams of Nonsaponifiable Material Derived From 12.5 Grams Of Fresh Yellow Bone Marrow."

NATURE OF CHARGE: *Yellow bone marrow concentrate.* Misbranding, Section 502 (a), certain statements on the bottle label and in a brochure attached to each bottle of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for chronic agranulocytosis and leukopenia. The article was not an adequate and effective treatment for such conditions.

Suprarenal concentrate capsules. Misbranding, Section 503 (b) (4), the article was a drug to which Section 503 (b) (1) did not apply, and its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

Further misbranding, Section 502 (f) (1), the labeling of the *yellow bone marrow concentrate* and the *suprarenal concentrate capsules* failed to bear adequate directions for use, and these articles were not entitled to any exemption from such requirement.

DISPOSITION: June 2, 1954. Default decree of condemnation and destruction.

4427. Misbranding of Mona-Serts vaginal tablets. U. S. v. 1,992 Boxes * * *. (F. D. C. No. 36812. Sample No. 86230–L.)

LIBEL FILED: May 28, 1954, Western District of Kentucky.

ALLEGED SHIPMENT: On or about June 1, 1952, by Strong, Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 1,992 boxes of *Mona-Serts vaginal tablets* at Louisville, Ky., in possession of the Wintersmith Chemical Co., Inc. A leaflet entitled "Mona-Serts Vaginal Tablets" was enclosed in each box.

RESULTS OF INVESTIGATION: In addition to the leaflet enclosed in each box, a number of leaflets entitled "Mona-Serts Vaginal Tablets Antiseptic—Fungicidal" had been printed locally for the consignee and were in his possession.

LABEL, IN PART: (Box) "24 Tablets Mona-Serts Vaginal Tablets Antiseptic—Fungicidal For the treatment of vaginal infections Each tablet contains: Aluminum Caprylate. . . . 3 grs. Phenylmercuric Acetate. . . . 0.3 mg. Urea. . . . 1.0 gr. In combination with Citric Acid, Boric Acid, Lactose and Dextrose."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the box label of the article and in the leaflet enclosed in each box were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for irritations of the vaginal tract, vaginal discharge, burning, chafing, and pruritis, and that it would restore normal physiological function of the vagina and re-establish the normal acidity of the vaginal tract. The article was not an adequate and effective treatment for such conditions and would not fulfill the promises of benefit stated and implied. Further misbranding, Section 503 (b) (4), the article was a drug to which Section 503 (b) (1) applied, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription." The article was misbranded in the above respects when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), certain statements in the leaflet entitled "Mona-Serts Vaginal Tablets Antiseptic—Fungicidal" accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for irritations of the vaginal tract, trichomonas vaginalis vaginitis, mycotic (monilia) vaginitis, and mixed infection vaginitis, and that it would restore normal physiological function of the vagina and re-establish the normal acidity of the vaginal tract. The article was not an adequate and effective treatment for such conditions and would not fulfill the promises of benefit stated and implied. The article was misbranded in such respect while held for sale after shipment in interstate commerce.

DISPOSITION: July 9, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4428. Misbranding of William's Yukol. U. S. v. 22 Bottles, etc. (F. D. C. No. 36517. Sample No. 84852-L.)

LIBEL FILED: April 21, 1954, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 15, 1953, and February 3 and March 19, 1954, from New York, N. Y.

PRODUCT: 22 2-ounce bottles, 52 4-ounce bottles, and 57 8-ounce bottles of *William's Yukol* at Philadelphia, Pa.

RESULTS OF INVESTIGATION: The product, after shipment in interstate commerce, was promoted for sale on the premises of a local Philadelphia store through spiels given by Mrs. Mitze Fanelli, who represented the product for various conditions. In addition to the sales talk, there were displayed on the sales counter 3 letters, each mounted separately on a square of cardboard, containing claims and representations for the product.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of headaches, migraine headaches, coughs, rheumatism, lumbago, neuritis, arthritis, backache, sinus trouble, fibrositis, myositis, and pain in the feet and legs, which were the conditions and purposes for which the article was offered to the public. The article was misbranded while held for sale after shipment in interstate commerce.

*See also Nos. 4423, 4426.

DISPOSITION: July 28, 1954. Default decree of condemnation and destruction.

4429. Misbranding of glandular products. U. S. v. 40 Vials, etc. (F. D. C. No. 36805. Sample Nos. 90071–L to 90077–L, incl., 90079–L.)

LIBEL FILED: On or about June 1, 1954, Western District of Missouri.

ALLEGED SHIPMENT: On or about August 2, 1951, November 28, 1952, November 16, 1953, and March 14 and 23, 1954, from Chicago, Ill.

PRODUCT: 40 vials of *pituitary anterior aqueous extract*, 60 vials of *ovarian aqueous extract*, 56 vials of *pituitary anterior and ovarian solution*, 20 vials of *orchic tissue aqueous extract*, 45 vials of *pituitary anterior and orchic solution*, 19 vials of *pituitary whole aqueous extract*, 52 vials of *ovarian residue aqueous extract*, and 74 vials of *Splcenx solution* at Kansas City, Mo., in possession of Henry C. Haist & Co., Inc. The size of each vial was 30 cc.

RESULTS OF INVESTIGATION: The products were shipped in bulk from Chicago, Ill., and upon receipt by the consignee, were repackaged and relabeled.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 9, 1954. Default decree of condemnation and destruction.

4430. Misbranding of aqueous extract of anterior pituitary. U. S. v. 698 Vials * * *. (F. D. C. No. 37023. Sample Nos. 61672–L to 61674–L, incl.)

LIBEL FILED: On or about August 3, 1954, Western District of Missouri.

ALLEGED SHIPMENT: On or about February 17 and March 17, 1953, from Chicago, Ill.

PRODUCT: 698 vials of *aqueous extract of anterior pituitary* at Kansas City, Mo., in possession of Ashe Lockhart, Inc. Some of the vials were labeled and some were unlabeled.

RESULTS OF INVESTIGATION: The article had been shipped in bulk from Chicago, Ill., and after its receipt by the consignee, was repackaged into vials.

LABEL, IN PART: (Vial) "10 c. c. Aqueous Extract Of Anterior Pituitary Each c. c. contains water soluble extractives from 18½ grains fresh tissue. Contains .5% Chlorobutanol (Chloroform Derivative). * * * Distributed by Ashe Lockhart, Inc. Kansas City, Mo."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, and it was not entitled to any exemption from such requirement. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 8, 1954. Default decree of destruction.

4431. Misbranding of orchic substance. U. S. v. 1 Canister, etc. (F. D. C. No. 36818. Sample No. 84853–L.)

LIBEL FILED: June 7, 1954, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 23, 1953, and March 1, 1954, from Chicago, Ill.

PRODUCT: 1 5-pound canister of *orchic substance in powder form* and 3 bottles containing *orchic substance in capsules* at Philadelphia, Pa., in possession of Fred F. Wanner & Sons.

RESULTS OF INVESTIGATION: The product, when shipped from Chicago, Ill., was in powder form and packaged in canisters. After receipt of the product by

the consignee, a portion was encapsulated and repackaged by the consignee into bottles.

LABEL, IN PART: (Bottle) "Capsules Orchic Substance Desiccated 10 Grains Average Dose Four to Six capsules daily. Caution—To be used only by or on the prescription of a physician Manufactured by Fred F. Wanner & Sons Philadelphia, Pa."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article in the canisters and in the bottles, namely, the label applied to the encapsulated powder, failed to bear adequate directions for use. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: August 4, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4432. Adulteration and misbranding of solution procaine with epinephrine. U. S. v. 25 Boxes * * *. (F. D. C. No. 36415. Sample No. 65385–L.)

LIBEL FILED: March 2, 1954, District of Minnesota.

ALLEGED SHIPMENT: Sometime prior to 1952, from Woodworth, Wis.

PRODUCT: 25 boxes, each containing 100 ampuls of *solution procaine with epinephrine* at Minneapolis, Minn.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Procaine Hydrochloride and Epinephrine Injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the official standard since it contained less than 95 percent of the labeled amount of procaine hydrochloride and had a pH lower than 3.3.

Misbranding, Section 502 (a), the label statement "Each 1 cc. Contains Procaine Hydrochloride U. S. P. (2%) . . . 0.02 gm." was false and misleading as applied to the article, which contained less than 0.02 gram of procaine hydrochloride per 1 cc..

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 23, 1954. Default decree of destruction.

4433. Adulteration and misbranding of tincture thimerosal. U. S. v. 69 Bottles * * *. (F. D. C. No. 36688. Sample No. 70900–L.)

LIBEL FILED: March 16, 1954, Southern District of Indiana.

ALLEGED SHIPMENT: On or about August 28, 1952, by Ransdell Co., Inc., from Louisville, Ky.

PRODUCT: 69 bottles of *tincture thimerosal* at Indianapolis, Ind. Analysis showed that the product contained 75 percent of the declared amount of thimerosal.

LABEL, IN PART: "One Gallon 3.78 Liters Tincture Thimerosal, N. N. R. 1:1000 Sodium Ethyl Mercuri Thiosalicylate (Thimerosal, N. F.) * * * Thimerosal, N. F. 0.1% * * * For External Use Only * * * Interstate Drug Company."

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*See also No. 4423.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 0.1 percent of thimerosal.

Misbranding, Section 502 (a), the label statements "Tincture Thimerosal * * * 1:1000" and "Thimerosal, N. F. 0.1" were false and misleading as applied to the article, which contained less than the stated amount of thimerosal.

DISPOSITION: May 20, 1954. Default decree of forfeiture and destruction.

4434. Adulteration and misbranding of tincture thimerosal. U. S. v. 10 Bottles * * *. (F. D. C. No. 36697. Sample No. 58328–L.)

LIBEL FILED: March 30, 1954, Northern District of Indiana.

ALLEGED SHIPMENT: On or about August 28, 1952, by Ransdell Co., Inc., from Louisville, Ky.

PRODUCT: 10 bottles of *tincture thimerosal* at Logansport, Ind. Analysis showed that the product contained 75 percent of the declared amount of thimerosal.

LABEL, IN PART: (Bottle) "One Gallon 3.78 Liters Tincture Thimerosal, N. N. R. 1:1000 Sodium Ethyl Mercuri Thiosalicylate (Thimerosal, N. F.) * * * Thimerosal, N. F. 0.1% * * * For External Use Only * * * Interstate Drug Company."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 0.1 percent of thimerosal.

Misbranding, Section 502 (a), the label statements "Tincture Thimerosal * * * 1:1000" and "Thimerosal N. F. 0.1" were false and misleading as applied to the article, which contained less than the stated amount of thimerosal.

DISPOSITION: May 26, 1954. Default decree of condemnation and destruction.

4435. Adulteration of adhesive bandages. U. S. v. 32 Boxes * * *. (F. D. C. No. 36743. Sample No. 66245–L.)

LIBEL FILED: May 12, 1954, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about November 12, 1953, by the United States Plastic Bandage Co., from Buffalo, N. Y.

PRODUCT: 32 boxes of *adhesive bandages* at Detroit, Mich.

LABEL, IN PART: "Contains 100 Bandages 1" X 3" Elast Aids Pliable Plastic Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive Absorbent Bandage," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since the article was not sterile.

DISPOSITION: July 13, 1954. The sole intervener having failed to file an answer, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4436. Misbranding of Hepavita tablets and Vitamin Formula tablets. U. S. v. Medical Discoveries, Inc., and Charles I. West, M. D. Plea of guilty by

*See also Nos. 4426, 4427, 4432–4434.

corporation and nolo contendere by individual. Sentence against corporation suspended. Individual fined $500 and sentenced to 8 months in jail; jail sentence suspended and placed on probation for 2 years. (F. D. C. No. 33792. Sample Nos. 54886-L, 54887-L.)

INFORMATION FILED: July 8, 1953, Eastern District of Michigan, against Medical Discoveries, Inc., Detroit, Mich., and Charles I. West, M. D., president of the corporation.

ALLEGED SHIPMENT: On or about December 5, 1952, from the State of Michigan into the State of Illinois.

LABEL, IN PART: (Bottle) "Hepavita 100 Tablets * * * Active Ingredients Methionine 100 mgs. Choline Bitartrate 200 mgs. Inositol 100 mgs." and "Medical Discoveries Vitamin Formula 100 Tablets * * * Contents Of Each Tablet Thiamine 5 mgs. Riboflavin 5 mgs. Niacinamide 25 mgs. B_{12} 1 mcgm. Niacin 5 mgs."

NATURE OF CHARGE: *Hepavita tablets.* Misbranding, Section 502 (a), certain statements on the bottle label, in the circular entitled "Now It Can Be Told!" and in the leaflet entitled "Directions For Taking Hepavita." accompanying the article, were false and misleading. The statements represented and suggested that the article would be an adequate and effective treatment and preventive for diseases of the kidneys, liver, blood vessels, heart, and other organs when such diseases are associated with high blood fat content; that it would be an adequate and effective treatment for arteriosclerosis, coronary heart disease, cirrhosis of the liver, alcoholism, diabetes, and other diseases associated with high blood cholesterols (blood fats); that it would dissolve blood fats and prevent damage to arteries and internal organs that might be caused by excessive fat in the blood stream; that it would prevent aging of blood vessels and vital organs; that it would keep the blood vessels and vital organs young; that it would prevent attacks of coronary disease, fatty infiltration of the liver, and further damage to the blood vessels in arteriosclerosis; that it would prevent further damage to the liver and other vital organs and repair damage due to alcoholism; that it would prevent artery disease in diabetes; that it would add years to one's life; that it would dissolve dangerous excessive fat particles in the blood stream and vital organs; that it would be an adequate and effective treatment for dizziness, failing memory, irritability, and loss of interest in life, hobbies, and loved ones; that it would bestow pep, energy, general well-being, vim, and vigor; that it would banish strain and fatigue; that it would fight against cerebral hemorrhage (commonly called "stroke") and fatal complications of diabetes; and that it would protect the heart, liver, and blood vessels against the damaging effects of alcohol. The article was not an adequate and effective treatment for such diseases, symptoms, and conditions, and it would not fulfill the promises of benefit stated and implied.

Vitamin Formula tablets. Misbranding, Section 502 (a), certain statements on the bottle label and in a leaflet entitled "Medical Discoveries Vitamin Formula Directions for Taking," accompanying the article, were false and misleading. The statements represented and suggested that the article, when used alone or in combination with another drug, namely, *Hepavita tablets*, would be adequate and effective as a prophylactic against aging; and that it would be adequate and effective in the treatment of coronary disease, liver disease, arteriosclerosis, and alcoholism, and in the prevention of artery disease

in diabetes. The article, when used alone or in combination with *Hepavita tablets*, would not be adequate and effective for such purposes.

DISPOSITION: June 23, 1954. The corporation having entered a plea of guilty and the individual having entered a plea of nolo contendere, the court suspended the imposition of sentence against the corporation, fined the individual $500, and sentenced him to 8 months in jail. The court also suspended the jail sentence against the individual and placed him on probation for 2 years.

4437. Misbranding of Duodex capsules. U. S. v. 348 Bottles, etc. (F. D. C. No. 36535. Sample Nos. 44196–L to 44198–L, incl., 44690–L.)

LIBEL FILED: April 29, 1954. District of Massachusetts.

ALLEGED SHIPMENT: On an unknown date, by Harris Laboratories, Inc., from Glen Cove, Long Island, N. Y.

PRODUCT: 348 100-capsule bottles and 1,348 50-capsule bottles of *Duodex capsules* at Boston, Mass.

LABEL, IN PART: (Bottle) "Duodex * * * Each capsule contains approximately 0.3 grams of desiccated and partially defatted duodenal substance processed to retain the ingredients believed to relieve ulcer pains and symptoms of ulcerative colitis."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in a circular designated "Duodex The New Effective Treatment For Peptic And Duodenal Ulcer Sufferers," enclosed with the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for ulcers, ulcer pains, healing the ulcer crater and restoring a normal intestinal lining, rebuilding the normal mucosal lining and smoothing over the raw eroded ulcer surface, repairing the ulcerated area, ulcerative colitis, indigestion, and gastritis. The article was not an adequate and effective treatment for such conditions and purposes.

DISPOSITION: July 20, 1954. Default decree of condemnation and destruction.

4438. Misbranding of Pyl-tone pile ointment. U. S. v. 2,000 Tubes, etc. (F. D. C. No. 36453. Sample No. 86111–L.)

LIBEL FILED: March 26, 1954, Northern District of Texas.

ALLEGED SHIPMENT: On or about March 13, 1952, from Bristol, Tenn.

PRODUCT: 2,000 unlabeled tubes of *Pyl-tone pile ointment* at Amarillo, Tex., in the possession of the Mergh Laboratories, together with a number of loose tube labels reading, in part, "Pyl-tone Pile Ointment" and a number of leaflets designated "The New Scientific Remedy for Piles Pyl-tone Ointment."

RESULTS OF INVESTIGATION: The unlabeled tubes of the product were packaged in labeled cartons when shipped from Bristol, Tenn. The above-mentioned loose labels and leaflets were printed for the Mergh Laboratories; and upon receipt of an order for the ointment, the Mergh Laboratories would apply 1 of the loose labels to a tube of ointment and enclose a copy of the above-mentioned leaflet.

LABEL, IN PART: (Carton) "Manufactured For: The Mergh Laboratories Amarillo, Texas Product Specification: S. F. #15,589 One Dozen – One Oz. Tubes (Unlabeled) Pyl-Tone Ointment Active Ingredients: Cedar Leaf Oil, Pokeroot, Bismuth Subgallate, Balsam Peru in a Castor Oil and White

Petroleum Base"; (loose label) "1 Oz. * * * Pyl-tone Pile Ointment * * * The Mergh Laboratories Distributors Box 2001—Amarillo, Texas."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for hard, unnatural growths in the rectum; conditions manifested by bleeding from the rectum; discharges from piles; and for dissolving blood clots in piles and drawing out poisonous fluids from the body. The article was not an adequate and effective treatment for such conditions and purposes. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 28, 1954. The Mergh Laboratories, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

4439. Misbranding of Bara Dermin and Bara Paraderm. U. S. v. 750 Cartoned Tubes, etc. (F. D. C. No. 36513. Sample Nos. 46085–L, 46086–L.)

LIBEL FILED: April 20, 1954, District of Rhode Island.

ALLEGED SHIPMENT: On or about September 17 and 25, 1953, by the Bara Farmacal Corp., from New York, N. Y.

PRODUCT: 750 cartoned tubes of *Bara Dermin* and 762 cartoned tubes of *Bara Paraderm* at Providence, R. I.

LABEL, IN PART: (Carton) "Bara Dermin 1 oz. Net Wt. Antiseptic Skin Balm * * * Contains: Pot. Hydroxyquinolin Sulph., Chlorocresol, Geraniol, Mineral Oil, Petrolatum, Oil-in-Water Emulsion" and "Bara Paraderm 2 Oz. Net Wt. Burn Ointment * * * Contains: Lanolin, Neatsfoot Oil, Olive Oil, Phenyl Salicylate, Cetyl Alcohol, in an Emollient Base."

NATURE OF CHARGE: *Bara Dermin.* Misbranding, Section 502 (a), certain statements on the carton label and in the leaflet bearing the words "Dermin Antiseptic Skin Balm New Advance In Skin Therapy," which was enclosed in each carton, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for rashes, pimples, itching, sores, boils, eczema, septic infections, and impetigo. The article was not an adequate and effective treatment for such conditions.

Bara Paraderm. Misbranding, Section 502 (a), certain statements on the carton label and in the leaflet bearing the words "Paraderm Instant Action Burn Ointment New Formula For Burn Therapy," enclosed in each carton of the article, were false and misleading. The statements represented and suggested that the article ensured an adequate and effective protection against X-rays and high frequency rays, such as atomic rays, and that the article constituted an adequate and effective treatment for burns. The article was not an adequate and effective protection against X-rays and high frequency rays, such as atomic rays, and was not an adequate and effective treatment for burns.

DISPOSITION: May 14, 1954. Default decree of condemnation and destruction.

4440. Misbranding of Ridd medicated powder. U. S. v. 9 Cases * * *. (F. D. C. No. 36727. Sample No. 67404–L.)

LIBEL FILED: May 3, 1954, Northern District of Texas.

ALLEGED SHIPMENT: On or about November 5, 1952, from Cleveland, Ohio. This was a return shipment.

PRODUCT: 9 cases, each containing 144 bottles, of *Ridd medicated powder* at Dallas, Tex. Analysis showed that the product contained boric acid.

LABEL, IN PART: (Bottle) "Ridd Medicated Powder * * * Net Weight 1 Oz. Manufactured By Ridd Laboratories Edmonds, Washington."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and display cartons were false and misleading. These statements represented and suggested that the article was an adequate and effective treatment for skin troubles, pimples, acne, barber's itch, skin itch, skin rash, ringworm, fungus, industrial skin irritations, boils, and varicose ulcers. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: June 8, 1954. Default decree of condemnation and destruction.

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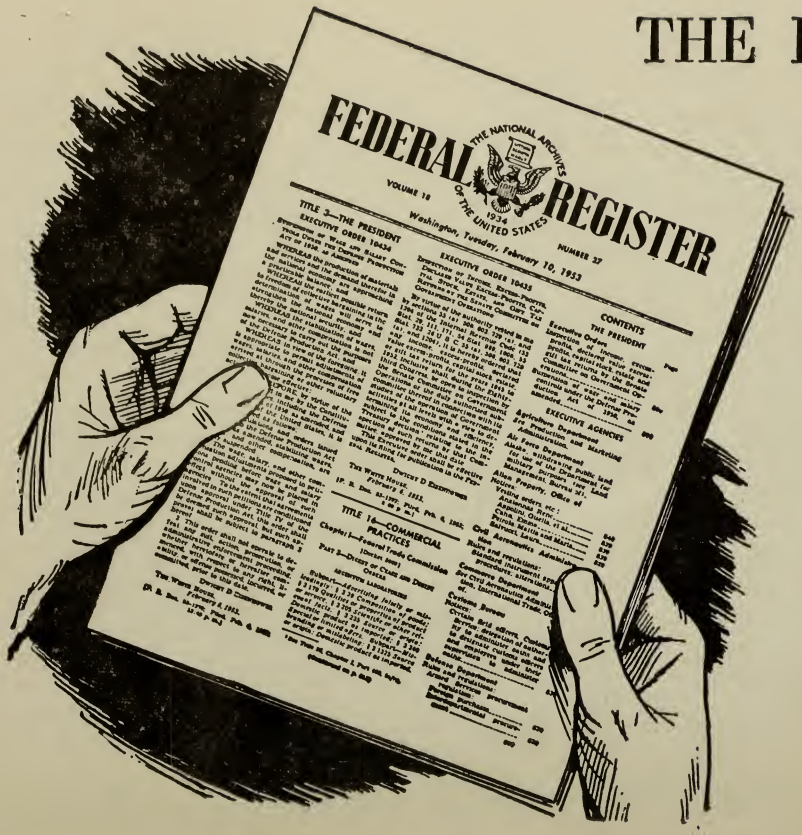

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4441–4460

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *August 19, 1955.*

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*For failure to comply with the packaging requirements of an official compendium, see No. 4457.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4441. Misbranding of amphetamine sulfate tablets. U. S. [redacted] (a partnership), William Mexic, Sam Mexic, and [redacted] E. Kugler. Plea of not guilty for Sam Mexic and pleas of nolo contendere for other defendants. Fine of $500 against partnership, $500 against William Mexic, and $250 against William E. Kugler. Sam Mexic tried to the court and found not guilty. (F. D. C. No. 35120. Sample Nos. 69011–L, 69012–L.)

INFORMATION FILED: June 2, 1953, Eastern District of Louisiana, against the Circle Drug Store, a partnership, New Orleans, La., and against William Mexic and Sam Mexic, partners in the partnership, and William E. Kugler, a pharmacist for the partnership.

NATURE OF CHARGE: On or about February 5 and 12, 1953, while a number of *amphetamine sulfate tablets* were being held for sale at the Circle Drug Store, after shipment in interstate commerce, various quantities of the drug were dispensed without a prescription from a practitioner licensed by law to administer such drug. The partnership, William Mexic, and Sam Mexic were charged with causing the acts of dispensing involved in each of the 2 counts of the information, and William E. Kugler was joined as a defendant in count 2 of the information. Such acts of dispensing were alleged to be contrary to Section 503 (b) (1) and to result in the dispensed drug being misbranded.

DISPOSITION: Sam Mexic entered a plea of not guilty, and the other defendants entered pleas of nolo contendere. On August 26, 1953, the court fined the partnership $500, William Mexic $500, and William E. Kugler $250. On July 1, 1954, the case against Sam Mexic came on for trial before the court without a jury. The trial was concluded on the same day, with the return of a verdict of not guilty for Sam Mexic.

4442. Misbranding of sulfadiazine tablets. U. S. v. Bates Drug Store, Bedford F. Bates, and Marion G. Phillips. Pleas of nolo contendere. Fine of $100 against defendants jointly. (F. D. C. No. 35812. Sample Nos. 81662–L to 81665–L, incl.)

INFORMATION FILED: March 8, 1954, Eastern District of Oklahoma, against the Bates Drug Store, a partnership, Wewoka, Okla., and Bedford F. Bates and Marion G. Phillips, partners in the partnership.

NATURE OF CHARGE: On or about October 21, 23, 26, and 28, 1953, while a number of *sulfadiazine tablets* were being held for sale at the Bates Drug Store, after shipment in interstate commerce, the defendants caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: June 7, 1954. The defendants having entered pleas of nolo contendere, the court imposed a fine of $100 against the defendants jointly.

4443. Misbranding of sulfadiazine tablets. U. S. v. Turner J. West (Keystone Drug Store). Plea of nolo contendere. Fine, $100. (F. D. C. No. 35801. Sample Nos. 81651–L to 81654–L, incl.)

INFORMATION FILED: March 8, 1954, Eastern District of Oklahoma, against Turner J. West, trading as Keystone Drug Store, Holdenville, Okla.

NATURE OF CHARGE: On or about October 21, 23, 26, and 28, 1953, while a number of *sulfadiazine tablets* were being held for sale at the Keystone Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: June 7, 1954. The defendant having entered a plea of nolo contendere, the court fined him $100.

4444. Misbranding of sulfathiazole tablets. U. S. v. Walter L. Brandon (Brandon Pharmacy). Plea of not guilty. Tried to the court and jury. Plea of guilty entered following introduction of Government's evidence. Defendant fined $300 and placed on probation for 3 years. (F. D. C. No. 35128. Sample Nos. 41537–L, 41550–L, 66959–L.)

INFORMATION FILED: July 22, 1953, Eastern District of Pennsylvania, against Walter L. Brandon, trading as Brandon Pharmacy, Philadelphia, Pa.

NATURE OF CHARGE: On or about January 23, 27, and 29, 1953, while a number of *sulfathiazole tablets* were being held for sale at the Brandon Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: The defendant having entered a plea of not guilty, the case came on for trial before the court and jury on June 9, 1954. After the Government had introduced its evidence, the defendant entered a plea of guilty. On July 7, 1954, the court fined the defendant $300 and placed him on probation for 3 years.

4445. Misbranding of sulfathiazole tablets. U. S. v. Sooner Drug, Arthur J. Christenson, and Jack L. Patrick. Pleas of nolo contendere. Fine of $75 against defendants jointly. (F. D. C. No. 35779. Sample Nos. 61846–L to 61848–L, incl.)

INFORMATION FILED: March 8, 1954, Eastern District of Oklahoma, against Sooner Drug, a partnership, Seminole, Okla., Arthur J. Christenson, a partner and manager of the partnership, and Jack L. Patrick, an employee.

NATURE OF CHARGE: On or about October 21, 23, and 26, 1953, while a number of *sulfathiazole tablets* were being held for sale at Sooner Drug, after shipment in interstate commerce, the defendants caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: June 7, 1954. Pleas of nolo contendere having been entered, the court imposed a fine of $75 against the defendants jointly.

4446. Misbranding of sulfathiazole tablets. U. S. v. Rex A. Hefner (Roberts Drug Store), and Nolen V. Williams. Pleas of nolo contendere. Fine of $100 against defendants jointly. (F. D. C. No. 35820. Sample Nos. 61832–L to 61835–L, incl.)

INFORMATION FILED: March 8, 1954, Eastern District of Oklahoma, against Rex A. Hefner, trading as Roberts Drug Store, Wewoka, Okla., and Noley V. Williams, a pharmacist.

NATURE OF CHARGE: On or about October 21, 23, 26, and 28, 1953, while a number of *sulfathiazole tablets* were being held for sale at the Roberts Drug Store, after shipment in interstate commerce, the defendants caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: June 7, 1954. The defendants having entered pleas of nolo contendere, the court imposed a fine of $100 against the defendants jointly.

4447. Misbranding of sulfathiazole tablets. U. S. v. Cecil H. Carter (Carter Owl Drug Store). Plea of nolo contendere. Fine, $75. (F. D. C. No. 35781. Sample Nos. 61837–L to 61839–L, incl.)

INFORMATION FILED: March 8, 1954, Eastern District of Oklahoma, against Cecil H. Carter, trading as the Carter Owl Drug Store, Seminole, Okla.

NATURE OF CHARGE: On or about October 21, 23, and 26, 1953, while a number of *sulfathiazole tablets* were being held for sale at the Carter Owl Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: June 7, 1954. The defendant having entered a plea of nolo contendere, the court fined him $75.

4448. Misbranding of tablets containing a mixture of sulfadiazine, sulfamerazine, and sulfamethazine. U. S. v. Parks Drug Store, Phillip G. Parks, and Henry M. Parks. Pleas of nolo contendere. Fine of $25 against store and Phillip G. Parks jointly on count 1, $25 against store and Henry M. Parks jointly on each of counts 2 and 3, and $25 against store on count 4. (F. D. C. No. 35780. Sample Nos. 61841–L to 61844–L, incl.)

INFORMATION FILED: March 8, 1954, Eastern District of Oklahoma, against Parks Drug Store, a partnership, Seminole, Okla., and Phillip G. Parks and Henry M. Parks, partners and pharmacists for the partnership.

NATURE OF CHARGE: On or about October 21, 23, 26, and 28, 1953, while a number of *tablets containing a mixture of sulfadiazine, sulfamerazine, and sulfamethazine* were being held for sale at the Parks Drug Store, after shipment in interstate commerce, various quantities of the drug were dispensed without a prescription from a practitioner licensed by law to administer such drug. The partnership was charged with causing the acts of dispensing involved in each of the 4 counts of the information; Phillip G. Parks was joined as a defendant in count 1; and Henry M. Parks was joined as a defendant in counts 2 and 3. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: June 7, 1954. Pleas of nolo contendere having been entered, the court imposed the following fines: $25 against the partnership and Phillip G. Parks jointly on count 1 of the information, $25 against the partnership and

Henry M. Parks jointly on each of counts 2 and 3, and $25 against the partnership on count 4.

4449. Misbranding of tablets containing a mixture of sulfadiazine, sulfamerazine, and sulfathiazole. U. S. v. Stanford Drug Store, Carl C. Stanford, and Harwell Daughtery. Pleas of nolo contendere. Fine of $100 against defendants jointly. (F. D. C. No. 35808. Sample Nos. 81657–L to 81660–L, incl.)

INFORMATION FILED: March 17, 1954, Eastern District of Oklahoma, against the Stanford Drug Store, a partnership, Holdenville, Okla., and Carl C. Stanford and Harwell Daughtery, partners in the partnership.

NATURE OF CHARGE: On or about October 21, 23, 26, and 28, 1953, while a number of *tablets containing a mixture of sulfadiazine, sulfamerazine, and sulfathiazole* were being held for sale at the Stanford Drug Store, after shipment in interstate commerce, the defendants caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: June 7, 1954. The defendants having entered pleas of nolo contendere, the court imposed a fine of $100 against the defendants jointly.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4450. Misbranding of ovarian substance. U. S. v. 31 Cartons * * *. (F. D. C. No. 36428. Sample No. 19750–L.)

LIBEL FILED: March 10, 1954, District of Minnesota.

ALLEGED SHIPMENT: On or about December 9, 1953, by the Vitamix Corp., from Philadelphia, Pa.

PRODUCT: 31 cartons, each containing one vial, of *ovarian substance* at Minneapolis, Minn.

LABEL, IN PART: (Carton and vial) "30 cc. Multiple Dose Vial Cat. No. 727 Canfield Ovarian Substance High Potency For Intramuscular Use Only * * * Each cc. contains the water soluble extraction of dried glands derived from: Whole Ovarian, fresh gland. . . . 40 grains Chlorobutanol (Chloral deriv.) 0.5% For Professional Use Only Sterile Solution Contains no known hormonal therapeutic activity. Caution: Federal law prohibits dispensing without prescription."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: June 23, 1954. Default decree of destruction.

4451. Misbranding of Senecol tablets. U. S. v. 86 Bottles * * *. (F. D. C. No. 36482. Sample No. 63626–L.)

LIBEL FILED: April 12, 1954, Southern District of Illinois.

ALLEGED SHIPMENT: On or about December 31, 1953, by Kenton Pharmacal Co., Inc., from Covington, Ky.

PRODUCT: 86 bottles of *Senecol* at Decatur, Ill.

LABEL, IN PART: (Bottle) "Senecol The Lipotropic-Tonic Tablet For The Aging (35 and over) * * * 100 Tablets The Kenton Pharmacal Co., Incorporated Covington, Kentucky Sole Owner and Distributor."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of iron-deficiency anemia, high blood pressure, hardening of the arteries, and premature aging, which were the conditions for which the article was intended and offered for sale.

DISPOSITION: July 29, 1954. Default decree of condemnation and destruction.

4452. Misbranding of hemorrhoidal suppositories and rectal ointment. U. S. v. 108 Boxes, etc. (F. D. C. No. 36460. Sample Nos. 89131–L, 89132–L.)

LIBEL FILED: March 24, 1954, District of Connecticut.

ALLEGED SHIPMENT: On or about August 31 and October 2, 1953, by G & W Laboratories, Inc., from Jersey City, N. J.

PRODUCT: 108 boxes of *hemorrhoidal suppositories* and 84 cartoned tubes of *rectal ointment* at Bridgeport, Conn.

LABEL, IN PART: (Box) "One Poster Dozen Hemorrhoidal Suppositories Formula: Istrian Nutgalls, Zinc Oxide, Ethyl Amino Benzoate in Cocoa Butter Base"; (tube) "1⅜ Oz. Poster Rectal Ointment For * * * Formula—Istrian nutgalls, zinc oxide, ethyl amino benzoate in petrolatum base."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading. The statements represented and suggested that the articles were an adequate and effective treatment for all forms of hemorrhoids and piles, whereas the articles were not an adequate and effective treatment for such conditions.

Further misbranding, Section 502 (f) (2), the labelings of the articles failed to bear warnings against use in the case of bleeding piles.

DISPOSITION: June 9, 1954. Default decree of condemnation and destruction.

4453. Misbranding of aloe leaves, Tropical salve, and papaya soap. U. S. v. Lloyd C. Shanklin. Plea of guilty. Fine of $200 on count 1; imposition of sentence suspended on counts 2 and 3 and defendant placed on probation for 2 years. (F. D. C. No. 35572. Sample Nos. 61096–L, 61098–L, 61099–L.)

INFORMATION FILED: May 6, 1954, Southern District of Florida, against Lloyd C. Shanklin, Homestead, Fla.

ALLEGED SHIPMENT: On or about November 3, 1952, and February 21, 1953, from the State of Florida into the State of Missouri.

LABEL, IN PART: "Inches Tropical Salve A Rich, Smooth Base In Which Is Mixed The Enzyme Papain, From The Tropical Papaya. 2½ oz. net weight Distributed only by Tropical House Corp., Marine Bldg., Riviera Beach, Fla." and "Howard Inches Papaya Soap West Palm Beach Florida."

NATURE OF CHARGE: *Aloe leaves.* Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article, namely, a booklet entitled "Chemical Types of People and Their Foods," were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for stomach disorders, indigestion, gastritis, ulcers, piles and hemorrhoids, fistulas, tumors, cancer, kidney troubles, cataract, arthritis, external ulcers, stomach ulcers, colitis, diabetes, burns, bruises, sprains, boils,

swelling of the joints, eczema, and athlete's foot. The article was not an adequate and effective treatment for such diseases and conditions. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes and conditions for which the article was intended, namely, for use in the treatment of blood poisoning, gangrene, gallstones, diabetes, blood tumors, fibroid tumors, shingles, tropical fever, glaucoma, stomach disorders, indigestion, gastritis, ulcers, piles and hemorrhoids, fistulas, tumors, cancer, kidney troubles, cataract, arthritis, external ulcers, stomach ulcers, colitis, diabetes, burns, bruises, sprains, boils, swelling of the joints, eczema, and athlete's foot.

Tropical salve. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes and conditions for which the article was intended, namely, for use in the treatment of external ulcers, blood poisoning, gangrene, and diabetes.

Papaya soap. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes and conditions for which the article was intended, namely, for use in the treatment of lines and wrinkles in the face and for diabetes.

DISPOSITION: July 16, 1954. The case having been transferred to the Western District of Missouri for the entry of a plea of guilty by the defendant and the defendant having subsequently entered such plea, the court fined the defendant $200 on count 1, suspended the imposition of sentence on counts 2 and 3, and placed the defendant on probation for 2 years.

4454. Misbranding of Vitozone ozone generator. U. S. v. 15 Devices * * *. (F. D. C. No. 36399. Sample No. 64737–L.)

LIBEL FILED: February 18, 1954, Western District of Washington.

ALLEGED SHIPMENT: On or about January 13, 1954, from Burbank, Calif.

PRODUCT: 15 *Vitozone ozone generators* at Seattle, Wash., in possession of H. I. Spencer doing business as the Vitozone Co. of Northwest.

The device consisted of an electrically operated device with glass tubes and the necessary electrical parts required to cause the tubes to glow and cause the formation of ozone in the surrounding air when the device was connected to household electric current.

RESULTS OF INVESTIGATION: During the course of sales talks made to prospective customers by sales representatives for H. I. Spencer, representations were made concerning the efficacy of the device for the conditions and purposes set forth below.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in the treatment of arthritis, sinusitis, tapeworm infestation, high blood pressure, cataract, pimples, colds, influenza, bursitis, deafness, eczema, coronary thrombosis, hardening of the arteries, varicose veins, multiple sclerosis, and paralysis of the leg, for providing good health, and for replenishing the oxygen supply of the blood, which were the conditions, purposes, and uses for which the device was intended and for which it was recommended in its oral advertising. The device was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: August 2, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4455. Adulteration of ammonium chloride tablets. U. S. v. 1 Drum * * *. (F. D. C. No. 36365. Sample No. 58343–L.)

LIBEL FILED: February 2, 1954, Northern District of Illinois.

ALLEGED SHIPMENT: On or about December 4, 1953, by the Shaw Pharmacal Co., from St. Louis, Mo.

PRODUCT: 1 drum containing 9,800 *ammonium chloride tablets* at Chicago, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ammonium Chloride Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality fell below the official standard. The standard specifies that a coating may be applied to ammonium chloride tablets, provided that such coating will disintegrate in the alimentary tract. The tablets of the article were so coated that they did not disintegrate in the alimentary tract.

DISPOSITION: May 12, 1954. Default decree of condemnation and destruction.

4456. Adulteration and misbranding of vitamin B complex. U. S. v. 25 Cartoned Vials * * *. (F. D. C. No. 36352. Sample No. 57938–L.)

LIBEL FILED: On or about January 21, 1954, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about May 25, 1951, from Decatur, Ill.

PRODUCT: 25 cartoned vials, 10–cc. size, of *vitamin B complex* at Richmond, Va. Analysis showed that the article contained 73 percent of the declared amount of vitamin B_1.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 50 milligrams of thiamine HCl per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc. contains: * * * Thiamine HCl . . . 50 mg." was false and misleading.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 21, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4457. Misbranding of liver injection. U. S. v. 119 Cartoned Vials * * *. (F. D. C. No. 36370. Sample No. 65384–L.)

LIBEL FILED: February 6, 1954, District of Minnesota.

ALLEGED SHIPMENT: On or about July 31, 1952, from New Brunswick, N. J.

PRODUCT: 119 cartoned vials, 10–cc, size, of *liver injection* at Minneapolis, Minn. Microbiological examination of the product indicated the presence of 8 micrograms of vitamin B_{12} per cubic centimeter.

NATURE OF CHARGE: Misbranding Section 502 (a), the label statement "Each cc. contains: 15 Units U. S. P. Injectable" was false and misleading as applied to the article, which contained 8 micrograms of vitamin B_{12} per cubic centimeter; and, Section 502 (g), the article purported to be "Liver Injection,"

*See also Nos. 4452, 4453, 4456.

a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the article was not labeled as prescribed in such compendium since its label failed to state the potency in terms of vitamin B_{12} activity, as the compendium requires. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 23, 1954. Default decree of destruction.

4458. Misbranding of Chilton's throat tablets. U. S. v. 39 Cartons * * *. (F. D. C. No. 36396. Sample No. 40042–L.)

LIBEL FILED: February 18, 1954, Southern District of California.

ALLEGED SHIPMENT: On or about January 12, 1954, by the Chilton Laboratories, from Montclair, N. J.

PRODUCT: 39 cartons, each containing 12 retail packages, of *Chilton's throat tablets* at North Hollywood, Calif.

LABEL, IN PART: (Carton) "Chilton's Throat Tablets * * * Sore Throat New Antibiotic * * * Tyrothricin * * * Recently authorized for sale to public by U. S. Government Agency (F. D. A)"; (retail package) "Chilton's * * * Throat Tablets. Each tablet contains 2 mg. of tyrothricin and 5 mg. benzocaine * * * For relief of Sore Throat due to minor irritations."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the carton and package labels of the article were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for sore throat, whereas the article was not an adequate and effective treatment for sore throat.

Further misbranding, Section 502 (a), the statement on the carton label of the article, namely, "Recently authorized for sale to public by U. S. Government Agency (F. D. A.)," was misleading since it represented and suggested that the article designated "Chilton's Throat Tablets" had been authorized for sale by the Food and Drug Administration under the labeling employed therefor, whereas such was contrary to fact.

DISPOSITION: April 21, 1954. Default decree of condemnation and destruction.

4459. Misbranding of electrotherapy device. U. S. v. 1 Device * * *. (F. D. C. No. 34928. Sample No. 42434–L.)

LIBEL FILED: April 6, 1953, Northern District of California.

ALLEGED SHIPMENT: On or about August 1, 1952, by Rittenhouse & Revere, Inc., from Albuquerque, N. Mex.

PRODUCT: 1 *electrotherapy device* at Salinas, Calif. The device was designed for vaporizing liquids and for producing galvanic, surge galvanic, sine wave, and faradic voltages.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "Physics" were false and misleading. The statements represented and suggested that use of the device constituted an adequate and effective treatment for adhesions, amenorrhea, anemia, aphonia, emphysema, bronchiectasis, bronchitis, cataracts, cerebral congestion, cervical laceration, cervicitis, stenosis of the cervix, cirrhosis of the liver, colitis, constipation, deafness, dysmenorrhea, endometritis, erosion of the cervix, stricture of the esophagus, granulated eyelids, fibroids, adolescent goiter, colloid goiter, herpes zoster, hypertension, hyperovarianism, intestinal stasis and ptosis, iritis, chronic nephritis, kraurosis vulvae, labyrinthitis, leukorrhea, mastitis,

menorrhagia, obesity, otitis media, ovarian cyst, ovarian tumor, polycythemia, prostate hypertrophy, prostatitis, dilatation and ptosis of the stomach, urethral strictures, scars, urethral ulceration, uterine subinvolution, and visceroptosis. Use of the device would not constitute an adequate and effective treatment for such diseases and conditions.

DISPOSITION: August 11, 1954. Rittenhouse & Revere, Inc., claimant, having filed an answer denying that the device was misbranded and later having withdrawn such answer, judgment of condemnation was entered and the court ordered that the product be delivered to the Food and Drug Administration.

4460. Misbranding of Tammen table. U. S. v. 1 Device, etc. (F. D. C. No. 34995. Sample No. 14693–L.)

LIBEL FILED: April 25, 1953, Northern District of Texas.

ALLEGED SHIPMENT: On or about April 28, 1952, by the Tammen Table Co., from Tucson, Ariz.

PRODUCT: 1 device known as a *Tammen table* at Lubbock, Tex., together with leaflets entitled "Tammen Tables."

The device consisted of a table, the top of which was divided into six individual padded sections. Four of the padded sections could be given a vibratory-rotatory motion by a ⅓-horsepower electric motor. Individual controls were provided to adjust the length of stroke and direction of rotation of each movable padded section. In addition, a pair of pedals on a rotating arm could be brought into position for use by a person lying on the table top.

LABEL, IN PART: "Tammen Table Oscillatable."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the article were false and misleading. The statements represented and suggested that the article would be effective to reduce overweight and normalize all body functions, whereas the article would not be effective for such purposes.

DISPOSITION: June 15, 1954. Kathleen Tammen, doing business as Tammen Tables, Tucson, Ariz., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the device be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

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PRODUCTS

[1] (4441, 4444) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4441, 4444) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1955

D. D. N. J., F. D. C. 4461–4480 Issued September 1955

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4461–4480

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *August 29, 1955.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

4461. Misbranding of secobarbital sodium capsules. U. S. v. Isadore M. Pressman. Plea of guilty. Defendant fined $500 and sentenced to 1 year in jail; jail sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 35570. Sample No. 75183–L.)

INDICTMENT RETURNED: March 29, 1954, District of Columbia, against Isadore M. Pressman, a pharmacist for the Randolph Pharmacy, Washington, D. C.

NATURE OF CHARGE: On or about February 2, 1954, while a number of *secobarbital sodium capsules* were being held for sale at the Randolph Pharmacy, after shipment in interstate commerce, the defendant caused a number of the capsules to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such act of dispensing was contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: June 11, 1954. The defendant having entered a plea of guilty, the court fined him $500 and sentenced him to 1 year in jail, but suspended the jail sentence and placed him on probation for 1 year.

4462. Misbranding of secobarbital sodium capsules and tablets containing a mixture of amobarbital and dextro-amphetamine sulfate. U. S. v. Bogard Drug Co. and Joseph A. Bogard. Pleas of nolo contendere. Fine of $400 against company, and $100 against individual, plus costs. (F. D. C. No. 35799. Sample Nos. 61994–L, 61995–L, 61998–L, 61999–L.)

INFORMATION FILED: March 31, 1954, District of Nebraska, against the Bogard Drug Co., a corporation, Omaha, Nebr., and Joseph A. Bogard, vice president of the corporation and manager of its store.

NATURE OF CHARGE: On or about October 27 and 29 and November 2 and 4, 1953, while a number of *secobarbital sodium capsules* and *tablets containing a mixture of amobarbital and dextro-amphetamine sulfate* were being held for sale at the Bogard Drug Co., after shipment in interstate commerce, the defendants caused various quantities of the drugs to be dispensed upon requests for refills of written prescriptions therefor without obtaining authorization by the prescriber. Such acts of dispensing were contrary to Section 503 (b) (1) , and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: May 13, 1954. Pleas of nolo contendere having been entered, the court imposed a fine of $400 against the corporation and $100 against the individual, plus costs.

4463. Misbranding of amphetamine sulfate tablets and tablets containing a mixture of sulfamerazine, sulfadiazine, sulfamethazine, and penicillin G potassium, with calcium carbonate and other excipients. U. S. v. Lester E. Downie and Grant Gardner. Pleas of guilty. Fine of $500 against Lester E. Downie and $350 against Grant Gardner. (F. D. C. No. 35569. Sample Nos. 64480–L, 64482–L, 64483–L.)

INFORMATION FILED: April 27, 1954, District of Oregon, against Lester E. Downie, manager and pharmacist for Taylor's Payless Drug Store, Ontario, Oreg., and against Grant Gardner, a pharmacist for the store.

NATURE OF CHARGE: On or about June 18, 24, and 29, 1953, while a number of *amphetamine sulfate tablets* and *tablets containing a mixture of sulfa-*

merazine, sulfadiazine, sulfamethazine, and penicillin G potassium, with calcium carbonate and other excipients were being held for sale at Taylor's Payless Drug Store, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Lester E. Downie was charged with causing the acts of dispensing involved in each count of the information, and Grant Gardner was joined as a defendant in count 3 of the information. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: July 16, 1954. Lester E. Downie having entered a plea of guilty to counts 1 and 2 of the information and Grant Gardner having entered a plea of guilty to count 3, the court fined Lester E. Downie $500 and Grant Gardner $350.

4464. Misbranding of pentobarbital sodium capsules and amphetamine sulfate tablets. U. S. v. Harry Rosenbloom (Rosenbloom Cut Rate Drugs). Plea of guilty. Fine of $500, plus costs. (F. D. C. No. 35825. Sample Nos. 63051–L, 63059–L.)

INFORMATION FILED: May 14, 1954, Eastern District of Missouri, against Harry Rosenbloom, trading as Rosenbloom Cut Rate Drugs, St. Louis, Mo.

NATURE OF CHARGE: On or about December 8 and 23, 1953, while a number of *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were being held for sale at Rosenbloom Cut Rate Drugs, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: May 28, 1954. The defendant having entered a plea of guilty, the court fined him $500, plus costs.

4465. Misbranding of methamphetamine hydrochloride tablets. U. S. v. Otto Gerstner. Plea of guilty. Fine, $200. (F. D. C. No. 35815. Sample No. 17603–L.)

INFORMATION FILED: May 24, 1954, Southern District of California, against Otto Gerstner, a pharmacist for the Federal Drug Co., San Diego, Calif.

NATURE OF CHARGE: On or about March 20, 1953, while a number of *methamphetamine hydrochloride tablets* were being held for sale at the Federal Drug Co., after shipment in interstate commerce, the defendant caused a number of the tablets to be dispensed upon request for a refill of a written prescription for the tablets, without obtaining authorization by the prescriber. Such act of dispensing was contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: July 19, 1954. The defendant having entered a plea of guilty, the court fined him $200.

4466. Misbranding of Gantrisin tablets, thyroid tablets, and Dexedrine Sulfate tablets. U. S. v. Anthony S. Carabillo (Wappingers Drug Store). Plea of guilty. Fine, $100. (F. D. C. No. 35834. Sample Nos. 51200–L, 51201–L, 51206–L to 51209–L, incl., 51224–L, 51225–L.)

INFORMATION FILED: June 7, 1954, Southern District of New York, against Anthony S. Carabillo, trading as Wappingers Drug Store, Wappingers Falls, N. Y.

NATURE OF CHARGE: On or about August 6, 13, 19, 20, 25, and 27, 1953, while a number of *Gantrisin tablets, thyroid tablets,* and *Dexedrine Sulfate tablets* were being held for sale, after shipment in interstate commerce, the defendant caused the misbranding, under Section 503 (b) (1), of the drugs by refilling prescriptions for the *Gantrisin tablets* and the *thyroid tablets* without authority from the prescriber and by dispensing the *Dexedrine Sulfate tablets* without a prescription from a practitioner licensed by law to administer such drug.

DISPOSITION: June 30, 1954. The defendant having entered a plea of guilty, the court fined him $100.

4467. Misbranding of capsules containing a mixture of ergot, apiol, oil pennyroyal, and aloin. U. S. v. Morris J. Heister (Regal Drug Co.). Plea of guilty. Defendant fined $250 and sentenced to 6 months in jail; jail sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 35819. Sample Nos. 85091–L, 85121–L.)

INFORMATION FILED: May 10, 1954, Eastern District of Pennsylvania, against Morris J. Heister, trading as the Regal Drug Co., Philadelphia, Pa.

NATURE OF CHARGE: On or about September 11 and October 16, 1953, while a number of *capsules containing a mixture of ergot, apiol, oil pennyroyal, and aloin* were being held for sale at the Regal Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the capsules to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such act of dispensing was contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: August 4, 1954. The defendant having entered a plea of guilty, the court fined him $250 and sentenced him to 6 months in jail, but suspended the jail sentence and placed him on probation for 2 years.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

4468. Misbranding of extract corpus luteum. U. S. v. 22 Cartoned Vials * * *. (F. D. C. No. 36815. Sample No. 45691–L.)

LIBEL FILED: May 26, 1954, District of Massachusetts.

ALLEGED SHIPMENT: On or about April 20, 1954, by Harvey Laboratories, Inc., from Philadelphia, Pa.

PRODUCT: 22 cartoned vials of *extract corpus luteum* at Fitchburg, Mass.

LABEL, IN PART: (Carton and vial) "H 30 cc Size Ampul-Vial Sterilized Soluble Extract Corpus Luteum Each cc. represents 1.0 Gm (15.4 grs.) whole Corpus Luteum, preserved with Chlorobutanol (Chloroform Derivative) 0.5%."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: July 26, 1954. Default decree of condemnation and destruction.

4469. Misbranding of anterior pituitary solution, Vitopit, suprarenal cortex solution, and Multiglands. U. S. v. 28 Vials, etc. (F. D. C. No. 36809. Sample Nos. 58647–L to 58650–L, incl.)

LIBEL FILED: May 26, 1954, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about July 17, 1953, and February 3, 10, and 18, 1954, by the Vitamix Corp., from Philadelphia, Pa.

PRODUCT: 28 vials of *anterior pituitary solution*, 64 vials of *Vitopit*, 47 vials of *suprarenal cortex solution*, and 468 vials of *Multiglands* at Detroit, Mich. The size of each vial was 30 cc.

Analyses showed that the *suprarenal cortex solution* and the *Multiglands* contained no significant quantity of protein.

LABEL, IN PART: (Vial) "30 cc. Multiple Dose Vial Anterior Pituitary Solution Sterile—Intramuscular Only * * * Each cc. contains the water soluble extraction of dried glands derived from: Anterior Pituitary, fresh gland 18½ grains"; "30 cc. Multiple Dose Vial Vitopit * * * Intramuscular Only * * * Each 2 cc. represents the water soluble extraction of dried glands derived from: Anterior Pituitary fresh gland. . . . 18½ grs. Ovarian Whole Gland fresh gland. . . . 40 grs. Procaine HCl. . . . 1%"; "30 cc. Multiple Dose Vial Suprarenal Cortex Solution Sterile—Intramuscular Only For Professional Use Only * * * Each cc. contains a water soluble extract of 2.5 gram of fresh Suprarenal Cortex Tissue * * * Indications: Foreign Protein Therapy"; and "30 cc. Multiple Dose Vial Multiglands (Plurigland Extract) Intramuscular Only * * * Each 2 cc. represents the water soluble extraction of dried glands derived from: Suprarenal Cortex, fresh gland. . . . 3.0 grs. Thyroid U. S. P. . . . 2.0 grs. Pituitary Anterior, fresh gland. . . . 1.0 grs. Pituitary Posterior, fresh gland. . . . 0.1 grs. Ovarian Substance, fresh gland. . . . 15.0 grs. Thymus, fresh gland. . . . 3.0 grs. Lymphatic, fresh gland. . . . 3.0 grs. * * * Indications: Non-Specific Protein Therapy."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use.

Further misbranding, Section 502 (a), the statement "Indications: Foreign Protein Therapy" on the label of the *suprarenal cortex solution* and the statement "Indications: Non-Specific Protein Therapy" on the label of the *Multiglands* were false and misleading since such statements represented and suggested that the articles were effective for providing foreign protein reaction therapy, which was contrary to fact.

DISPOSITION: July 13, 1954. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

4470. Misbranding of anterior pituitary extract. U. S. v. 297 Boxes * * *. (F. D. C. No. 36424. Sample No. 81734–L.)

LIBEL FILED: March 18, 1954, District of Nebraska.

ALLEGED SHIPMENT: On or about April 23, 1952, from Chicago, Ill.

PRODUCT: 297 boxes, each containing 1 vial, of *anterior pituitary extract* at Lincoln, Nebr., in possession of Norden Laboratories.

RESULTS OF INVESTIGATION: The product was shipped in bulk from Chicago, Ill., and after its receipt by the consignee, it was repackaged and relabeled.

LABEL, IN PART: (Box) "Norden 10 cc Size Aqueous Extract of Anterior Pituitary"; (vial) "10 cc Size Aqueous Extract of Anterior Pituitary Caution: To be dispensed only by or on the prescription of a veterinarian. Packaged for Norden Laboratories Lincoln, Nebraska Each cc contains water-soluble extractives from 18½ grains fresh tissue. Chlorobutanol (Preserva-

tive), 0.5% * * * Dosage: Horses and Cattle, 5 to 10 cc; Sheep and Swine, 2 to 4 cc; Small Animals, ½ to 2 cc, depending upon size. Inject subcutaneously or intramuscularly B 319."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 2, 1954. Default decree of condemnation and destruction.

4471. Misbranding of anterior pituitary extract and ovarian residue extract. U. S. v. 1,463 Vials, etc. (F. D. C. No. 36807. Sample Nos. 15904–L, 15905–L.)

LIBEL FILED: On or about May 28, 1954, Western District of Missouri.

ALLEGED SHIPMENT: On or about February 26 and July 8, 1953, and March 7 and 31, 1954, from Chicago, Ill.

PRODUCT: 1,463 vials of *anterior pituitary extract* and 651 vials of *ovarian residue extract* at Kansas City, Mo., in possession of Jensen-Salsbery Labs., Inc. Some of the vials were labeled and some were unlabeled.

RESULTS OF INVESTIGATION: The products had been shipped in bulk from Chicago, Ill., and upon receipt by the consignee, they had been repackaged and, in part, relabeled.

LABEL, IN PART: (Vial) "Anterior Pituitary Extract 10 cc. Jen-Sal * * * Prepared from the fresh Anterior Pituitary Lobe, each cc. representing 18½ gr. of gland substance. Preserved with 0.5% Chlorobutanol (Chloroform derivative). Packaged By Jensen-Salsbery Laboratories, Inc. Kansas City, Missouri * * * No claim is made for hormonal activity. Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian," and "Ovarian Residue Extract 25 cc. Jen-Sal * * * Concentrated An aqueous solution, each cc. representing the water soluble extractives from 40 grs. (2.6 Gms.) of fresh ovarian residue. Chlorobutanol 0.5% as a preservative Sold exclusively to veterinarians. Packaged By Jensen-Salsbery Laboratories, Inc. Kansas City, Missouri."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 9, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4472. Adulteration and misbranding of phenobarbital tablets. U. S. v. 420,000 Tablets * * *. (F. D. C. No. 36545. Sample No. 80521–L.)

LIBEL FILED: May 3, 1954, District of New Jersey.

ALLEGED SHIPMENT: On or about April 15, 1954, from Philadelphia, Pa. This was a return shipment.

PRODUCT: 420,000 *phenobarbital tablets* in 2 drums at Hoboken, N. J. Analysis showed that the product contained 74.4 percent of the declared amount of phenobarbital.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely ¼ grain of phenobarbital per tablet.

Misbranding, Section 502 (a), the label statement "Each tablet contains: * * * Phenobarbital ¼ Grain" was false and misleading.

DISPOSITION: July 1, 1954. Default decree of condemnation and destruction.

4473. Adulteration and misbranding of Crystar aspirin. U. S. v. 137 Cartons * * *. (F. D. C. No. 36543. Sample No. 67792–L.)

LIBEL FILED: April 30, 1954. Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about February 10, 1954, from Dallas, Tex.

PRODUCT: 137 cartons, each containing 24 packets, of *Crystar aspirin* at New Orleans, La. Analysis showed that the product contained less than the 1 grain of aspirin per packet declared on the label.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1 grain of pure aspirin per packet.

Misbranding, Section 502 (a), the label statement "1 grain of pure Aspirin" was false and misleading as applied to the article, which contained less than 1 grain of pure aspirin per packet.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 5, 1954. Default decree of condemnation and destruction.

4474. Adulteration and misbranding of Glucatinic tablets. U. S. v. 946 Bottles * * *. (F. D. C. No. 36509. Sample No. 52509–L.)

LIBEL FILED: April 20, 1954, District of New Jersey.

ALLEGED SHIPMENT: On or about January 18, 1954, by Summers Laboratories, Inc., from Ambler, Pa.

PRODUCT: 946 bottles of *Glucatinic tablets* at East Orange, N. J. Analysis showed that the product contained 74 percent of the declared amount of vitamin B_1.

LABEL, IN PART: (Bottle) "100 Tablets No. 1255 Glucatinic Sugar Coated Red Each tablet contains: * * * Thiamine Hydrochloride (B_1) 1 mg. * * * For the treatment of iron-deficiency anemia, accompanied by vitamin B complex deficiencies."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 1 milligram of vitamin B_1 per tablet.

Misbranding, Section 502 (a), the label statement "Each tablet contains: * * * Thiamine Hydrochloride (B_1) 1 mg." was false and misleading as applied to a product which contained less than 1 milligram of vitamin B_1 per tablet.

DISPOSITION: May 26, 1954. Default decree of condemnation and destruction.

4475. Adulteration and misbranding of adhesive bandages. U. S. v. 125 Cartons * * *. (F. D. C. No. 36308. Sample No. 84131–L.)

LIBEL FILED: February 8, 1954, District of Minnesota.

ALLEGED SHIPMENT: On or about August 21, 1953, by the Hampton Manufacturing Co., from New Rochelle, N. Y.

PRODUCT: 125 cartons, each containing 12 boxes, of *adhesive bandages* at Mankato, Minn.

LABEL, IN PART: (BOX) "12 Waterproof Blue Cross Sterile Adhesive Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the quality and purity of the article fell below the official standard since the article was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterile" was false and misleading.

DISPOSITION: October 1, 1954. A default decree was entered providing for destruction by the marshal, on or before October 30, 1954, of the 214 cartons of the product actually seized, unless prior to that time the product be given to a charitable institution with the understanding that it be sterilized before using.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE *

4476. Misbranding of Biochemic homeopathic drugs. U. S. v. 10 Boxes, etc. (F. D. C. No. 36407. Sample Nos. 64379–L to 64389–L, incl.)

LIBEL FILED: March 26, 1954, Western District of Washington.

ALLEGED SHIPMENT: At various times during 1953, by the Kansas City Homeopathic Pharmacy, from Kansas City, Mo.

PRODUCT: 10 boxes of *Biochemic No. 1*, 43 boxes of *Biochemic No. 2*, 38 boxes of *Biochemic No. 3*, 17 boxes of *Biochemic No. 4*, 24 boxes of *Biochemic No. 5*, 36 boxes of *Biochemic No. 7*, 17 boxes of *Biochemic No. 8*, 23 boxes of *Biochemic No. 9*, 10 boxes of *Biochemic No. 10*, 25 boxes of *Biochemic No. 11*, and 13 boxes of *Biochemic No. 12*, at Everett, Wash., in possession of June's Food Store, together with accompanying labeling consisting of a booklet designated "Indications For The Use of Dr. Schussler's Twelve Tissue Remedies The More Common Diseases and Their Treatment * * * Compiled and Arranged by Julius C. Wise, M. D. * * * Kansas City, Missouri." Each box contained 1 ounce.

RESULTS OF INVESTIGATION: The products were shipped in bulk from Kansas City, Mo., and upon their receipt by the consignee, were repackaged and relabeled. The above-mentioned booklet was issued by the shipper of the products and was made available by the consignee for the use of customers in selecting the above-mentioned drugs for self-treatment of various diseases.

LABEL, IN PART: (BOX) "Biochemic No. 1 Active Ingredient Calcium Floride," "Biochemic No. 2 Active Ingredient Calcium Phosphate," "Biochemic No. 3 Active Ingredient Calcium Sulphate," "Biochemic No. 4 Active Ingredient Iron Phosphate," "Biochemic No. 5 Active Ingredient Potassium Chloride," "Biochemic No. 7 Active Ingredient Potassium Sulphate," "Biochemic No. 8 Active Ingredient Magnesium Phosphate," "Biochemic No. 9 Active Ingredient Chloride of Sodium," "Biochemic No. 10 Active Ingredient Phosphate of Soda," "Biochemic No. 11 Active Ingredient Sodium Sulphate," and "Biochemic No. 12 Active Ingredient Silica."

*See also Nos 4469, 4472–4475.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklet accompanying the articles were false and misleading since the articles were not adequate and effective treatments for the diseases, conditions, and purposes stated and implied. The statements represented and suggested—

(a) That the *Biochemic No. 1* was an adequate and effective treatment for tumors, piles, varices, varicose veins, aneurism, relaxed uvula, prolapse of womb, opacities of cornea, ganglion, hard lumps in female breast, lumpy, hard, horny growths of the tissues, cracked hands, hardened mammary glands, glandular swellings, cataract, sagging abdomen, hardened exudations, induration of testicle, suppuration, psoriasis, ozaena, knots, backache, bone bruises, cough, and catamenia.

(b) That the *Biochemic No. 2* was an adequate and effective treatment for rachitis, craniotabes, chlorosis, hydrocephalus, deficient development of children and young people, emaciation without apparent cause, suppuration of bones, uniting fractured bones, spinal weakness and curvature, teething disorders, improper development of teeth, rapid decay, convulsions of scrofulous persons, and as a restorative after acute diseases.

(c) That the *Biochemic No. 3* was an adequate and effective treatment for suppurations, abscesses, boils, buboes, suppurating burns and scalds, carbuncles, felons, pustules, milk crusts, mastitis, discharge of matter from the ear, expectoration of pus, gonorrhea, quinsy, sore throat, ulcerations of glands, and ulcers on legs.

(d) That the *Biochemic No. 4* was an adequate and effective treatment for all congestions, inflammations, fevers, rheumatism, vomiting, cough, colds, hemorrhages, hemorrhoids, congestive headache, incontinence of urine from weak sphincter, congestion, croup, deafness, diarrhea, earache, erysipelas, swellings, gonorrhea, gum boils, fever, palpitation, quinsy, scarlet fever, sprains, and wounds.

(e) That the *Biochemic No. 5* was an adequate and effective treatment for croup, diphtheria, dysentery, pneumonia, chronic catarrh, coughs, deafness from catarrh of eustachian tubes, skin eruptions with small vesicles, ulcerations, leucorrhea, coryza, constipation, ear diseases, chancre, dropsy, excoriation, gastritis, gonorrhea, hemorrhoids, hoarseness, whooping cough, liver diseases, lungs, measles, meningitis, menstruation, mumps, orchitis, pimples, pleurisy, childbed fever, fevers, rheumatism, scarlet fever, sick headache, swellings, sycosis, sore throat, and quinsy.

(f) That the *Biochemic No. 7* was an adequate and effective treatment for bronchitis, skin diseases, scarlet fever, dandruff, dyspepsia, catarrh of the stomach, catarrh of the bowels, diarrhea, leucorrhea, ophthalmia, and too late or too scanty menstruation.

(g) That the *Biochemic No. 8* was an adequate and effective treatment for all diseases having their origin in the nerve cells or in the terminal bulbs of the nerves, spasms, cramps, St. Vitus's dance, epilepsy, spasmodic retention of urine, colic, paralysis, neuralgic pains in the head, face, teeth, stomach, and abdomen, labor pains, menstrual colic, ovarian pains, puerperal states, palsy, stricture, squinting, difficult dentition, tetanus, and trembling.

(h) That the *Biochemic No. 9* was an adequate and effective treatment for headache, toothache, face ache, stomach ache, catarrhal affections of mucous membranes, small watery blisters, hay fever, diarrhea, conjunctivitis, and leucorrhea.

(i) That the *Biochemic No. 10* was an adequate and effective treatment for acidity, sour belching and rising of fluids, sour vomiting, diarrhea, colic, spasms, fever, ague, gastric derangement, heartburn, indigestion, and intestinal worms.

(j) That the *Biochemic No. 11* was an adequate and effective treatment for biliousness, excess of bile, bitter taste, greenish brown or grayish green tongue, bilious vomiting, vomiting of bile, jaundice, dropsy from diseases of the liver and scarlatina, bilious headache, intermittent fever, diabetes, erysipelas, gravel, polyuria, and edema of prepuce and scrotum.

(k) That the *Biochemic No. 12* was an adequate and effective treatment for paralytic conditions in general, profuse night sweats, caries, necrosis, inflammation, swelling and bending of bones (rachitis), scrofulous complaints, ailments following vaccination, ulcerations of all kinds, felons, fistula, glandular swellings, ulcerative consumption with expectorations of pus, lacrimal fistula, and constipation.

The articles were misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: August 2, 1954. Default decree of condemnation and destruction.

4477. Misbranding of alfalfa seed. U. S. v. 69 Bags, etc. (F. D. C. No. 36436. Sample Nos. 83824–L, 83825–L.)

LIBEL FILED: March 8, 1954, District of North Dakota.

ALLEGED SHIPMENT: Between the approximate dates of January 1 and July 1, 1953, from Moorhead, Minn.

PRODUCT: 69 unlabeled 1-pound bags and 69 labeled 1-pound envelopes of *alfalfa seed* at Fargo, N. Dak., in possession of the Fargo Seed House.

RESULTS OF INVESTIGATION: The product was shipped in bulk from Moorhead, Minn., and after its receipt by the Fargo Seed House, it was repackaged and a portion was relabeled.

LABEL, IN PART: (Envelope) "Sunland Grown Alfalfa For Tea 'Fargo Seed House' Fargo, N. Dak."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article, namely, in a clipping of an advertisement from a local newspaper on display on the show case in the store of the Fargo Seed House, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritis and rheumatism, whereas the article was not an adequate and effective treatment for such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 20, 1954. Default decree of condemnation. The court ordered that the product in the labeled envelopes be destroyed and that the product in the unlabeled bags be sold.

4478. Misbranding of Whitmer's Black Diamond liniment, Whitmer's Red Carminative, and Whitmer's Eureka. U. S. v. H. C. Whitmer Co. and Fred C. Whitehouse. Pleas of not guilty. Tried to the jury. Verdicts of guilty for company and not guilty for individual. Fine of $750, plus costs, against company. (F. D. C. No. 34344. Sample Nos. 11119–L, 11120–L, 11122–L.)

INFORMATION FILED: April 2, 1953, Southern District of Indiana, against the H. C. Whitmer Co., a corporation, Columbus, Ind., and Fred C. Whitehouse, president of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of May 10, 1950, and March 30, 1951, from the State of Indiana into the State of Ohio.

LABEL, IN PART: (Bottles) "Whitmer's Black Diamond Liniment * * * Active Ingredients: Turpentine Fractions, Linseed Oil, Camphor, Pine Oil," "Whitmer's Red Carminative * * * Active Ingredients: Red Pepper, Gum Camphor, Oil Cloves, Oil Cinnamon, Carbonate Soda," and "Whitmer's Eureka Alcohol 15% * * * Active Ingredients: Buchu, Uva Ursi, Culver Root, Juniper Berries, Alexander Senna, Caraway Seed, Gentian Root, Cape Aloes, Hydrangea, Soda Benzoate, Soda Acetate."

NATURE OF CHARGE: *Whitmer's Black Diamond liniment.* Misbranding, Section 502 (a), certain statements on the bottle labels and in accompanying circulars entitled "Whitmer Pep" and dated October 19 and November 2 and 9, 1950, and January 18 and February 1 and 8, 1951, were false and misleading. The statements represented and suggested that the article would be adequate and effective in the cure, mitigation, and treatment in man of wounds, burns, sprains, frost bites, muscular rheumatic pains, neuralgia, bruises, and cuts; that the article would be adequate and effective in the cure, mitigation, and treatment in animals of sore shoulders, sprains, bruises, and wounds, and in the prevention of blood poisoning and lockjaw in animals; and that the article would be adequate and effective in the cure, mitigation, and treatment of garget in cows and "summer eczema" in dogs. The article would not be adequate and effective for such purposes.

Whitmer's Red Carminative. Misbranding, Section 502 (a) certain statements on the bottle labels and in the accompanying circulars entitled "Whitmer Pep" and dated May 4, June 1, July 20, August 17, October 12 and 19, and November 9, 1950, and May 31, 1951, were false and misleading. The statements represented and suggested that the article would be adequate and effective in the treatment of cramps in women and young girls and sore throats in humans; that the article would be adequate and effective in the cure, mitigation, and treatment in humans, animals, and poultry of indigestion, nausea, sick stomach, acute indigestion, toothache, colic, diarrhea, unexpected illness, dyspepsia, flatulence, dysentery, chills, colds, and la grippe; that the article would increase the circulation of blood in humans, animals, and poultry; that the article may save life and that it would be adequate and effective in the cure, mitigation, and treatment of scours in colts, calves, and sheep, bowel trouble in chicks, and in the prevention of diseases in older fowls. The article would not be adequate and effective for the purposes and would not fulfill the promises of benefit stated and implied.

Whitmer's Eureka. Misbranding, Section 502 (a), certain statements on the bottle labels and in accompanying circulars entitled "Whitmer Pep" and dated August 17, November 9, and December 28, 1950, were false and misleading. The statements represented and suggested that the article would be adequate and effective in the treatment of chronic constipation, cleaning out the bowels and stomach, and flushing the urinary tract. The article would not be adequate and effective for such purposes.

DISPOSITION: Pleas of not guilty having been entered by the defendants, the case came on for trial before the court and jury on May 3, 1954. The trial was concluded on May 7, 1954, with the return by the jury of a verdict of

guilty for the corporation and a verdict of not guilty for the individual. On June 15, 1954, the court fined the corporation $750, plus costs.

4479. Misbranding of Polorator device. U. S. v. 20 Cartoned Devices, etc. (F. D. C. No. 36183. Sample Nos. 58891–L, 58898–L.)

LIBEL FILED: December 11, 1953, Northern District of Indiana.

ALLEGED SHIPMENT: On or about September 30, October 7 and 19, and December 4, 1953, by the Vogt Health Appliance Co., from Kalamazoo, Mich.

PRODUCT: 20 cartoned *Polorator devices* at Fort Wayne, Ind., together with a number of pamphlets entitled "Only the Polorator has Twin Pole Vibrators" and "The Polorator Application and Instructions," a number of cards entitled "Zone Therapy Chart," a number of books entitled "Stories The Feet Can Tell," a number of leaflets entitled "An Entirely New Low Priced Instrument for Beauticians," and a number of display placards entitled "Polorator Double Action massage with mild heat," "Try Now! This 3 Minute Test on your aches & pains No Charge," "Free Massage over these areas Sinus Hay Fever Asthma Arthritis Neuritis Tired Feet Reducing Areas," and "The Polorator World's Most Flexible Massage With Infra-Red Heat."

The *Polorator device* consisted essentially of a housing containing electromagnetic coils that operated 2 vibrating metal knobs which protruded from the housing. There was included with the device a wooden handle and footstool arrangement for applying the device to the body.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned pamphlets, cards, books, leaflets, and display placards accompanying the device were false and misleading. The statements represented and suggested that the device would provide an adequate and effective treatment for nervous and physical tensions, sinus conditions, arthritis, neuritis, overweight, fibrous swelling or infiltration in the interior of the body, bony or cartilaginous growth in the joints, tired, droopy feeling, poor circulation, aching joints, bursitis, kidney conditions, gallbladder conditions, muscular disturbances, organic disturbances, hay fever, asthma, congestion of the appendix, ileocecal valve conditions, pneumonia, conditions affecting the spleen, anemia, glaucoma, deafness, sore throat, enlarged tonsils, thyroid conditions, exophthalmic goiter, glandular trouble, enlarged prostate, diabetes, eczema, heart conditions, liver conditions, varicose veins, Bright's disease, dropsy, lumbago, apoplexy, rectal disorders, hemorrhoids, prolapsed rectum, and inflammation of the bladder. The device did not provide an adequate and effective treatment for such conditions.

DISPOSITION: July 8, 1954. Default decree of condemnation. The court ordered that the devices and their accompanying labeling be turned over to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

4480. Misbranding of Dr. Mayfield poultry tonic. U. S. v. 2 Drums, etc. (F. D. C. No. 33133. Sample No. 48320–L.)

LIBEL FILED: May 17, 1952, District of Minnesota.

ALLEGED SHIPMENT: On or about July 23, 1951, and April 1, 1952, by Dr. Mayfield Laboratories, Inc., from Charles City, Iowa.

PRODUCT: 2 drums of *Dr. Mayfield poultry tonic* at Osakis, Minn., together with a number of booklets entitled "Poultry Disease."

LABEL, IN PART: "Dr. Mayfield Poultry Tonic 100 Pounds Active Ingredients: Iron Oxide, Arsenic Trioxide 2%, Sulphates of Copper 20%, Aluminum, Manganese, Cobalt, Magnesium Carbonate, Fenugreek, Wild Mustard, Anise Seed and Potassium Iodide."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklet accompanying the article were false and misleading. The statements represented and suggested that the article would act as a stimulant, thereby increasing feed consumption and weight in slow birds, would clear up failures in the functions of the heart and kidneys, would promote proper digestion, would stimulate all organs and offset any poisonous effect produced by selenium, and was an adequate and effective treatment for kidney and muscle disturbances, mycotic infections, bowel disorders, pullet disease, and mycosis. The article was not effective for such purposes.

DISPOSITION: Dr. Mayfield Laboratories, Inc., appeared as claimant and filed an answer denying that the product was misbranded. Thereafter, the Government served written interrogatories and requests for admissions upon the claimant, which subsequently were answered. On July 1, 1954, with the consent of the claimant, judgment of condemnation was entered and the court ordered that the product be destroyed.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4461 TO 4480

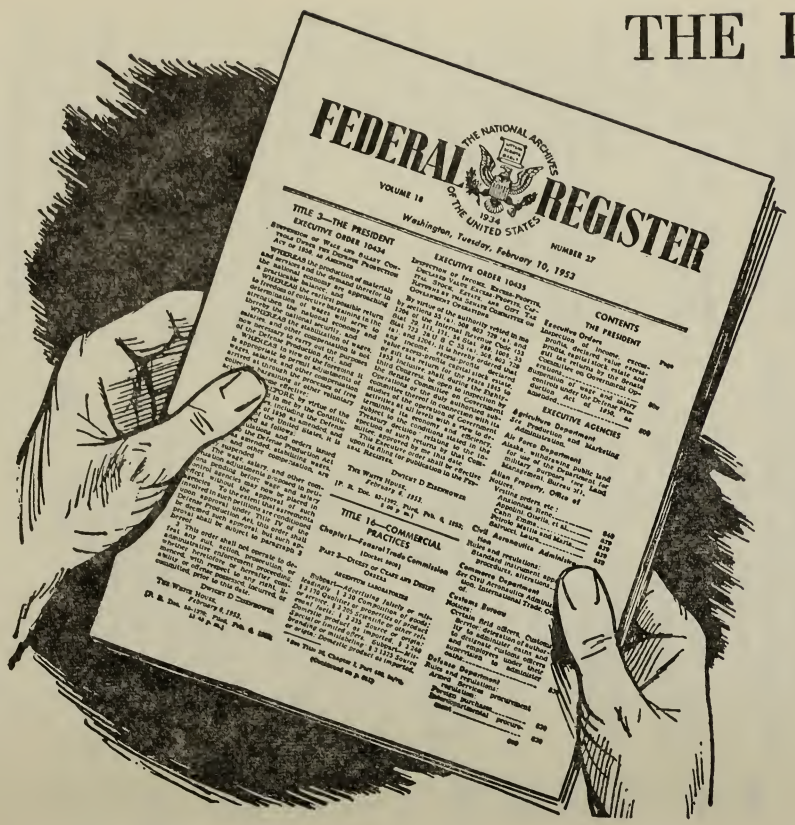
PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4478) Prosecution contested.

[1] (4478) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1955



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D. D. N. J., F. D. C. 4481–4500 Issued October 1955

U. S. Department of Health, Education, and Welfare

[redacted]

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4481–4500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *October 10, 1955.*

CONTENTS*

*For cosmetic, actionable under the drug provisions of the Act, see No. 4500.

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NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

4481. ACTH-Gel and Adrenocaps. U. S. v. 15 Cartoned [redacted] (and one other seizure action). (F. D. C. Nos. 36552, 36558. [redacted] to 58099–L, incl.)

LIBELS FILED: May 6, 1954, Northern District of Illinois.

ALLEGED SHIPMENT: On or about October 2 and 5 and November 4, 1953, by United Research Laboratories, Inc., from Philadelphia, Pa.

PRODUCT: 20 cartoned vials of *ACTH–Gel* and 10 bottles of *Adrenocaps* at Chicago and La Grange Park, Ill.

LABEL, IN PART: (Carton and vial) "(United Research) 10 cc. Multiple Dose Vial—Sterile ACTH-GEL (Corticotropin in Gelatin) 20 U. S. P. Units per cc. Caution: New drug limited by Federal Law to investigational use * * * Contains: 0.5% Phenol"; (bottle) "50 Tablets Adrenocaps with Cortisone Acetate Each tablet contains: Ammonium Salicylate. . . . 4 gr. Para-Aminobenzoic Acid (as the Potassium Salt). . . . 5 gr. Cortisone Acetate. . . . 3 mg. Salicylamide. . . . 1 gr. Enteric Coated * * * Caution: New Drug—Limited by Federal Law to Investigational Use."

NATURE OF CHARGE: Section 505 (a), the articles were new drugs within the meaning of the law, and applications filed pursuant to the law were not effective with respect to such drugs.

DISPOSITION: October 26 and 27, 1954. Default decrees of condemnation and destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4482. Misbranding of Gantrisin tablets, thyroid tablets, and sulfose tablets. U. S. v. Salvatore D'Avella. Plea of guilty. Fine, $50. (F. D. C. No. 36576. Sample Nos. 50508–L, 50509–L, 51195–L, 51196–L, 51883–L, 51885–L.)

INFORMATION FILED: June 14, 1954, Southern District of New York, against Salvatore D'Avella, trading as Decker Pharmacy, Catskill, N. Y.

NATURE OF CHARGE: On or about August 19, 20, 25, and 26, 1953, while a number of *Gantrisin tablets*, *thyroid tablets*, and *sulfose tablets* were being held for sale after shipment in interstate commerce, the defendant caused the misbranding of various quantities of *Gantrisin tablets* and *thyroid tablets* by refilling prescriptions for such drugs without authority from the prescriber, and caused also the misbranding of quantities of *sulfose tablets* by dispensing such tablets without a prescription from a practitioner licensed by law to administer such drug. Such acts were contrary to Section 503 (b) (1).

DISPOSITION: June 21, 1954. The defendant having entered a plea of guilty, the court fined him $50.

4483. Misbranding of thyroid tablets, Gantrisin tablets, and Combisul tablets. U. S. v. Albert Mikhitarian and Fred J. Muller. Pleas of guilty. Fine of $150 against Albert Mikhitarian and $25 against Fred J. Muller. (F. D. C. No. 35826. Sample Nos. 50473–L, 50475–L, 50484–L, 50485–L, 50489–L.)

INFORMATION FILED: June 14, 1954, Southern District of New York, against Albert Mikhitarian, trading as Mikhitarian's Pharmacy, Catskill, N. Y., and Fred J. Muller, a pharmacist.

NATURE OF CHARGE: On or about July 29 and August 19, 20, and 25, 1953, while a number of *thyroid tablets*, *Gantrisin tablets*, and *Combisul tablets* were being held for sale after shipment in interstate commerce, Albert Mikhitarian caused the misbranding of quantities of *thyroid tablets* and *Gantrisin tablets* by refilling prescriptions for such drugs without authority from the prescriber, and Fred J. Muller caused the misbranding of additional quantities of *thyroid tablets* and *Gantrisin tablets* by refilling prescriptions for such drugs without authority from the prescriber. Fred J. Muller caused also the misbranding of a quantity of *Combisul tablets* by dispensing such tablets without a prescription from a practitioner licensed by law to administer such drug. Such acts were contrary to Section 503 (b) (1).

DISPOSITION: June 22, 1954. Pleas of guilty having been entered, the court fined Albert Mikhitarian $150 and Fred J. Muller $25.

4484. Misbranding of thyroid tablets, Tricombisul tablets, and Tuinal capsules. U. S. v. Evan H. Boardman. Plea of guilty. Fine, $25. (F. D. C. No. 35823. Sample Nos. 50495–L, 50504–L, 51178–L.)

INFORMATION FILED: June 8, 1954, Southern District of New York, against Evan H. Boardman, a pharmacist at Catskill, N. Y.

NATURE OF CHARGE: On or about August 19, 20, and 25, 1953, while a number of *Tricombisul tablets*, *Tuinal capsules*, and *thyroid tablets* were being held for sale after shipment in interstate commerce, the defendant caused the misbranding, under Section 503 (b) (1), of such drugs by refilling prescriptions for *Tuinal capsules* and *thyroid tablets* without authority from the prescriber and by dispensing the *Tricombisul tablets* without the prescription of a practioner licensed by law to administer such drug.

DISPOSITION: July 1, 1954. The defendant having entered a plea of guilty, the court fined him $25.

4485. Misbranding of thyroid tablets and Neotrizine tablets. U. S. v. George Meyers and Arthur Karuzas. Pleas of guilty. Fine of $100 against George Meyers and $50 against Arthur Karuzas. (F. D. C. No. 36577. Sample Nos. 50512–L to 50514–L, incl., 50518–L to 50520–L, incl.)

INFORMATION FILED: June 15, 1954, Southern District of New York, against George Meyers, trading as Meyers Village Pharmacy, Wappingers Falls, N. Y., and Arthur Karuzas, a pharmacist in the pharmacy.

NATURE OF CHARGE: On or about July 30 and August 13, 19, 20, 25, and 27, 1953, while a number of *thyroid tablets* and *Neotrizine tablets* were being held for sale, various quantities of the drugs were caused to be misbranded by the refilling of prescriptions therefor without authority from the prescriber. George Meyers was charged with causing the misbranding of the drugs involved in each of the 6 counts of the information, and Arthur Karuzas was joined as a defendant in two of the counts. Such acts were contrary to Section 503 (b) (1).

DISPOSITION: June 23, 1954. The defendants having entered pleas of guilty, the court fined George Meyers $100 and Arthur Karuzas $50.

4486. Misbranding of Seconal Sodium capsules. U. S. v. Cathedral Chemists, a partnership, and Seymour Rabinowitz and Meyer Wiener. Pleas of guilty. Fine of $150 against partnership and Meyer Wiener jointly and $50 against Seymour Rabinowitz. (F. D. C. No. 35752. Sample Nos. 51213–L to 51217–L, incl.)

INFORMATION FILED: June 9, 1954, Southern District of New York, against Cathedral Chemists, a partnership, New York, N. Y., and Meyer Wiener, a partner in the partnership, and Seymour Rabinowitz, a pharmacist.

NATURE OF CHARGE: On or about April 24 and May 5, 12, 19, and 27, 1953, while a number of *Seconal Sodium capsules* were being held for sale after shipment in interstate commerce, the defendants caused the misbranding of various quantities of such capsules by refilling a prescription therefor without authority from the prescriber. Such act was contrary to Section 503 (b) (1).

DISPOSITION: July 1, 1954. The defendants having entered pleas of guilty, the court imposed a fine of $150 against the partnership and Meyer Wiener jointly and a fine of $50 against Seymour Rabinowitz.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

4487. Misbranding of Vigor-Tabs. U. S. v. Arthur Rubin (Arbin Products). Plea of guilty. Fine $450. (F. D. C. No. 36660. Sample Nos. 50578–L, 51526–L, 62849–L, 67733–L, 82734–L, 89210–L.)

INFORMATION FILED: November 29, 1954, Southern District of Florida, against Arthur Rubin, trading as Arbin Products, Miami, Fla.

ALLEGED SHIPMENT: Between the approximate dates of January 12 and April 15, 1954, from the State of Florida into the States of Arkansas, New York, Pennsylvania, and Alabama.

LABEL, IN PART: (Box) "Vigor-Tabs for the relief of normal fatigue Directions Adults: One tablet a day taken with water. For stubborn cases, take two tablets. Contents: Thiamin, Riboflavin, Nicatinamin, Pyridoxine, Calcium, Pantothenic Acid, and Nicotinin Acid. Arbin Products—Miami, Florida" and "40 Tablets Vigor-Tabs For temporary relief of normal fatigue Directions Adults: One tablet taken with a glass of water. For stubborn cases repeat in 2 or 3 hours. Caution: May produce sleeplessness if taken late in the evening. Contents: Caffeine Alkaloid Arbin Products, Inc. 612 S. W. 13th Street Miami, Florida."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the tablets were false and misleading. The statements represented and suggested that the tablets, when used as directed, would be effective to provide vigor and relieve normal fatigue, whereas the tablets, when used as directed, would not provide vigor and relieve normal fatigue.

Further misbranding, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use for the purposes and conditions for which the tablets were intended, namely, for use as an aphrodisiac and to restore sexual vigor, which were the purposes and conditions for which the tablets were offered in newspaper advertisements sponsored by and on behalf of the defendant.

DISPOSITION: December 3, 1954. The defendant having entered a plea of guilty, the court fined him $450.

4488. Misbranding of whole ovarian substance, suprarenal cortex liquid, and anterior pituitary substance. U. S. v. 14 Vials, etc. (F. D. C. Nos. 37033, 37034. Sample Nos. 15941–L to 15944–L, incl.)

LIBEL FILED: August 6, 1954, Northern District of Oklahoma.

ALLEGED SHIPMENT: The *suprarenal cortex liquid* and the 14-vial lot of *whole ovarian substance* were shipped by the Coast Chemical Co., from Los Angeles, Calif., on or about February 9, 1953, and June 21, 1954. The *anterior pituitary substance* and the 15-vial lot of *whole ovarian substance* were shipped by the American Bio-Chemical Corp., from Los Angeles, Calif., on or about April 26 and June 25, 1954.

PRODUCT: 14 vials and 15 vials of *whole ovarian substance*, 25 vials of *suprarenal cortex liquid*, and 21 vials of *anterior pituitary substance* at Tulsa, Okla.

LABEL, IN PART: (Vial) "30 cc Sterile Solution Whole Ovarian Substance Each cc contains the water soluble extractives derived from 80 grains of fresh whole ovarian tissue. Chlorobutanol—0.5% Caution: To be dispensed only by or on the prescription of a physician * * * Note: There is no scientific evidence available that this product has therapeutic or physiological activity," "30 cc Sterile Solution Suprarenal Cortex Liquid Each cc contains the extractives derived from 77½ grains of fresh Suprarenal Cortex tissue. Chlorobutanol—(as preservative)—0.5% Caution: Federal law prohibits dispensing without prescription * * * Intermuscular Injection No claims are made for hormone activity," "Anterior Pituitary Substance Each cc contains the water soluble extractives derived from 40 grains of fresh anterior pituitary lobe. Chlorobutanol—0.5% Caution: Federal law prohibits dispensing without prescription * * * For Intramuscular Use There is no scientific evidence available that this product has therapeutic or physiologic activity," "30 cc Sterile Solution Whole Ovarian Substance Each cc contains the water soluble extractives derived from 40 grains of whole ovarian tissue. Chlorobutanol—0.5% For Intramuscular Use Only Caution: Federal law prohibits dispensing without prescription. Note: There is no scientific evidence available that this product has therapeutic or physiologic activity."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemption from that requirement.

DISPOSITION: September 2, 1954. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

4489. Misbranding of aqueous extract of anterior pituitary. U. S. v. 335 Boxes * * *. (F. D. C. No. 36876. Sample No. 71002–L.)

LIBEL FILED: July 12, 1954, Southern District of Indiana.

ALLEGED SHIPMENT: On or about January 19, 1954, by the Maurry Biologicals Co., from Los Angeles, Calif.

PRODUCT: 335 boxes, each containing 1 vial of *aqueous extract of anterior pituitary* at New Castle, Ind.

LABEL, IN PART: (Box and vial) "Arnold * * * 10 cc Anterior Pituitary Aqueous Sterile Extract Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian. Distributed by Arnold Laboratories, New Castle, Ind. * * * Give Intramuscularly Large Animals 5 to 10 cc. Small Animals ½ to 1 cc Each cc contains the water soluble extractive from 18½ grains of fresh anterior pituitary."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: September 2, 1954. Default decree of forfeiture and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4490. Adulteration and misbranding of chorionic gonadotropin. U. S. v. 200 Packages * * *. (F. D. C. No. 36878. Sample No. 80671–L.)

LIBEL FILED: July 14, 1954, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 22, 1953, from Los Angeles, Calif.

PRODUCT: 200 packages, each containing 1 vial, of *chorionic gonadotropin* and 1 vial of diluent at Philadelphia, Pa. Examination showed that the strength of the article was less than 50% of that which it was represented to possess.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the statements "Chorionic Gonadotropin * * * 5,000 I. U." appearing on the package label and "Chorionic Gonadotropin—Vials, 5,000 I. U. in dry form" appearing on the package insert were false and misleading as applied to the article, which contained less than 2,500 International Units of chorionic gonadotropin activity per vial.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 6, 1954. Default decree of condemnation and destruction.

4491. Adulteration and misbranding of Poya-Liver Stronger. U. S. v. 11 Vials * * *. (F. D. C. No. 36857. Sample No. 48090–L.)

LIBEL FILED: July 2, 1954, Middle District of Alabama.

ALLEGED SHIPMENT: On or about January 12, 1954, by Testagar & Co., Inc., from Detroit, Mich.

PRODUCT: 11 vials of *Poya-Liver Stronger* at Montgomery, Ala. Analysis showed that the product contained less than 60 percent of the declared amount of vitamin B_{12}.

LABEL, IN PART: (Vial) "10 cc. No. 414A Poya-Liver Stronger Liver–Folic Acid–B_{12} Combination Intramuscular Use * * * Each cc. contains: * * * Vitamin B_{12} . . . . . 60 mcg. * * * For use in the treatment of all types of anemia other than hypochromic."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 60 micrograms of vitamin B_{12} per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc. contains: * * * Vitamin B_{12} . . . . . 60 mcg." was false and misleading.

DISPOSITION: July 27, 1954. Default decree of condemnation and destruction.

4492. Adulteration of adhesive bandages. U. S. v. 6 Cases * * *. (F. D. C. No. 36730. Sample No. 42774–L.)

LIBEL FILED: May 4, 1954, Northern District of California.

ALLEGED SHIPMENT: On or about February 25, 1954, by the U. S. Plastic Bandage Co., from Buffalo, N. Y.

PRODUCT: 6 cases, each containing 48 boxes, of adhesive bandages at San Francisco, Calif.

LABEL, IN PART: (Box) "Contains 100 Bandages ¾" x 3" Elast Aids Pliable Plastic Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive Absorbent Bandage," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the quality and purity of the article fell below the official standard since the article was not sterile.

DISPOSITION: August 2, 1954. The U. S. Plastic Bandage Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Department of Health, Education, and Welfare.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4493. Misbranding of Neuravim capsules. U. S. v. 10,722 Boxes, etc. (F. D. C. No. 34922. Sample No. 51322–L.)

LIBEL FILED: March 31, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about February 13, 1953, from Detroit, Mich., by the Freshman Vitamin Co., upon instructions from Neuravim Co., Ltd., Toronto, Canada.

PRODUCT: 10,722 boxes, each containing 45 capsules, of *Neuravim* at Jersey City, N. J., in possession of American Book-Stratford Press, Inc., together with a number of books entitled "The Neuravim Formula For Dynamic Nerve Power," a number of reorder blanks headed "Not Available To Anyone Other Than Neuravim Course Subscribers," and a number of booklets entitled "How To Eat For Nerve Power," "What To Eat For Nerve Power," "Sleep For Nerve Power," "Internal Hygiene For Nerve Power," "Exercises For Nerve Power," "Habits For Nerve Power," "Putting Nerve Power into Action," and "Neuravim The Power Within You."

RESULTS OF INVESTIGATION: The above-described books and booklets were printed by the consignee upon instructions from Neuravim Co., Ltd., and the reorder blanks were received by the consignee from such company. Upon instructions from Neuravim Co., Ltd., the consignee would assemble into packages, for mailing to customers, 1 book, 4 boxes of capsules, and 1 reorder blank.

LABEL, IN PART: (Box) "The Neuravim Formula Neuravim Conditioner Not for Medicinal Use Neuravim A preparation but not a substitute for the Nerve Power building program laid down by the Neuravim Directives, and is to be regarded as an adjunct but ancillary to the entire Neuravim course, and to be used accordingly. Each Capsule contains at time of Manufacture: Lac. Albumin Hydrolysate 250 Mg. L. Glutamic Acid 300 Mg. Soybean Lecithin 300 Mg. Vitamin E (d-alpha tocopherol acetate from Vegetable Oils) 25

*See also Nos. 4487, 4490, 4491.

I. U. Vitamin B_1 (Thiamine Hydrochloride USP) 2.5 Mg. Vitamin B_2 (Riboflavin USP) 3.33 Mg. Vitamin B_{12} USP 2 Mcg. Vitamin B_6 (Pyridoxine Hydrochloride) 0.5 Mg. Niacin Amide USP 50 Mg. Calcium Pantothenate 5 Mg. with excipients to properly prepare. * * * Directions: * * * Distributed By The Neuravim Company, Ltd., 8 West 40th St., New York 18, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the box label, the above-mentioned book, the reorder blanks, and the booklets accompanying the article, was false and misleading. This labeling contained statements, which, when taken as a whole, as well as in specific statements and when read in the light of the setting in which it was intended to be read, conveyed to the public a meaning which represented and suggested that the article would build nerve power and that it was an adequate and effective remedy for mental and physical distress, nervous breakdown, torments, personality defects that have destroyed or threaten to destroy capacity to earn a living, inability to cope with modern civilization's drain on nerve power, inability to summon reserve of nerve power to meet great opportunities or sudden emergencies, indecision, inferiority complexes, lack of will power, procrastination, nervousness, timidity, and immaturity; lack of self reliance, self-respect, and self control; poor memory, inability to concentrate, constant tiredness, worry, sexual weakness, and impotency; to prevent high blood pressure, ulceration, asthma, hay fever, acne, eczema, migraine headaches, gallstones, diabetes, colitis, constipation, diarrhea, digestive disorders, most heart diseases, backache, sciatica, rheumatism, arthritis, bursitis, "a long list of female disorders from menstrual disorders to serious conditions requiring hysterectomy," illnesses of germ and virus origin, sixty percent or more of illnesses, nervous breakdown, sleeplessness, fretfulness, loss of appetite, phobias such as fear of the dark or of crossing a bridge, confused thinking, impaired sight, deathlike appearance of the eyes, inability to focus the eyes, dulled hearing and taste senses, fear of insanity, heart palpitation, vertigo, severe depression, and suicidal tendencies; to assure a vigorous old age; to keep glands, organs, and faculties operating efficiently into old age; to supply the various factors contributing to nerve power; and to bridge "the gap which existed in man's conception of the functions of his body and his nervous system." The article would not build nerve power; it was not an adequate and effective treatment for the diseases and conditions stated and implied; and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: March 8, 1954. Charles Lee, as licensed trustee in behalf of the estate of Neuravim Co., Ltd., a bankrupt having appeared as claimant and consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Food and Drug Administration.

On June 11, 1954, an amended decree was entered which provided that in lieu of the release of the product under bond, the United States marshal should retain custody of the product and permit the claimant to relabel it while in custody.

4494. Misbranding of Immun capsules. U. S. v. 1,000 Bottles, etc. (F. D. C. No. 36192. Sample No. 49655–L.)

LIBEL FILED: January 7, 1954, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 10, 1953, from Detroit, Mich.

PRODUCT: 1,000 bottles of *Immun capsules* at Lynbrook, N. Y., in possession of Nu-Health Laboratories, Inc., together with a number of circulars entitled "Immun Capsules with Activator X A New Nutrient Factor" and a number of leaflets entitled "Read How Immun Capsules . . . with . . . Activator X Helped."

RESULTS OF INVESTIGATION: The capsules were shipped in interstate commerce in bulk, and upon receipt by the consignee, were repackaged and relabeled. The above-mentioned circulars and leaflets were printed locally for the consignee.

LABEL, IN PART: (Bottle) "Immun Capsules with the Essential Nutrient Factor Activator X Quantity 100 Capsules * * * Each Capsule Contains: 1700 USP units of Vitamin A 34% minimum daily requirement 170 USP units of Vitamin D 42% minimum daily requirement 222 milligrams of Activator X*

*Activator X is the Nu-Health Laboratories trademark for essential fatty acid fractions which have been found helpful in certain deficient or unbalanced conditions of body metabolism."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Immun Capsules with the Essential Nutrient Factor Activator X * * * essential fatty acid fractions which have been found helpful in certain deficient or unbalanced conditions of body metabolism" were false and misleading. The statements represented and suggested that the article would be effective in providing the user with immunity from ill-health and disease and that the article would supply essential nutrient factors, in addition to vitamins A and D, which would be effective to treat deficient or unbalanced conditions of body metabolism. The article was not effective for such purposes.

Further misbranding, Section 502 (a), certain statements in the above-mentioned circulars and leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was effective in the prevention and treatment of dental caries, colds, arthritis, joint and muscle stiffness, general debility, loss of appetite, underweight, gastritis, belching, anemia, insomnia, low blood pressure, disturbed vision, painful menses, constipation, general fatigue, cancer, chronic diseases, and bronchial colds, and that the article would provide more effective utilization of all nutritive elements. The article was not effective for such purposes.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: October 20, 1954. Nu-Health Laboratories, Inc., claimant, having filed an answer and later having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

4495. Misbranding of Fisher's Gas-Gon tablets. U. S. v. 20 Cases, etc. (F. D. C. No. 36801. Sample No. 58177–L.)

LIBEL FILED: May 21, 1954, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about March 14 and April 13 and 20, 1951, from Bryan, Ohio.

PRODUCT: 20 cases, each containing 12 cartons and each carton containing 12 100-tablet bottles and 100 free sample envelopes, of *Fisher's Gas-Gon tablets* at Detroit, Mich., in possession of the Gas-Gon Products Co. (Fisher's Cut Rate Drugs), together with a number of circulars designated "Wonderful New Gas-Gon Tablets."

RESULTS OF INVESTIGATION: The tablets contained in the envelopes were received in bulk and were repackaged and relabeled by the consignee. The above-mentioned circulars were printed by the consignee and were displayed on the counter in the consignee's store. In addition, the consignee had on display the following: a sign painted on outside of store building reading as follows: "Try Fisher's Gas-Gon for Quick Relief of Gas Pains Excess Acid and Ulcerated Stomach Satisfaction Guaranteed"; a streamer in the store window reading as follows: "Gas-Gon for ulcerated stomach due to gas & acid $2.89"; and a sign in the store over the prescription room reading as follows: "Why Suffer? Fisher's Gas-Gon 'Gone is Gas and Stomach Acid' Try This New Amazingly Fast Relief for Gas, Hyperacidity Pain due to Ulcers, Indigestion Sour Stomach and Similar Disturbances Satisfaction Guaranteed."

LABEL, IN PART: (Bottle and envelope) "Fisher's Gas-Gon Tablets Bisected Each tablet contains Dried Aluminum Hydroxide Gel Magnesium Hydrate Oil of Peppermint For the relief of hyperacidity and accompanying stomach discomforts."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the above-mentioned circulars, signs, and window streamer were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for stomach ulcers and similar disturbances, whereas the article was not an adequate and effective treatment for such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 16, 1954. Jacob S. Fisher, doing business as Fisher's Cut Rate Drugs and the Gas-Gon Products Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

4496. Misbranding of Hocking's Formula capsules and Hocking's Liquid. U. S. v. Hocking Drug Co., Inc. Plea of nolo contendere. Fine, $26. (F. D. C. No. 35577. Sample Nos. 69330–L, 76048–L, 76049–L.)

INFORMATION FILED: June 14, 1954, Eastern District of Washington, against Hocking Drug Co., Inc., Spokane, Wash.

ALLEGED SHIPMENT: On or about May 15 and July 6, 1953, from the State of Washington into the States of Colorado and Oregon.

PRODUCT: Analysis showed that the *Hocking's Formula capsules* contained acetanilid and aspirin and that the *Hocking's Liquid* contained sodium bromide, potassium iodide, sodium salicylate, and alcohol.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the articles namely, a leaflet entitled "Hocking Rheumatic Remedy For All Forms of Rheumatism" were false and misleading. The statements represented and suggested that the liquid and the capsules would be an adequate and effective treatment for rheumatism in all its forms, gout, arthritis, neuritis, sciatica, and lumbago, whereas the articles would not be an adequate and effective treatment for such conditions.

DISPOSITION: September 7, 1954. The defendant having entered a plea of nolo contendere, the court fined it $26.

4497. Misbranding of Gottschall's Life Essence tablets. U. S. v. 13,250 tablets, etc. (F. D. C. No. 36090. Sample No. 41629–L.)

LIBEL FILED: November 2, 1953, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 15, 1953, from Cleveland, Ohio.

PRODUCT: 13,250 *Gottschall's Life Essence tablets* in 1 drum and 650 bottles, each containing 55 similar tablets, at Harrisburg, Pa., in possession of Gottschall Products Co., Inc., together with a number of loose labels.

RESULTS OF INVESTIGATION: The tablets in the drum and in the bottles had been originally shipped in interstate commerce in bulk, and upon receipt by the consignee, a portion of the tablets was repacked into the above-mentioned bottles. The loose labels were for use in repackaging the tablets remaining in the drum.

LABEL, IN PART: (Bottle) "Gottschall's Life Essence Directions For Dyspepsia and Indigestion take 1 Tablet after meals. For Gastritis and Sour Stomach take 1 Tablet half hour before meals. For Toxic Poisoning, Malaria and General Run-Down Condition take 1 Tablet after meals and at night. Take treatment until relieved. If dose taken becomes too active on the bowels, lessen; if not sufficient, increase. Children 10 yrs. or over ½ tablet. 5 yrs to 10 yrs. ¼ tablet. * * * Net Weight Each Tablet 4 grains Contains Gentian Root Pepsin Pancreatin Myrrh Senna Alose Drop Black Saffron Oil Peppermint Powdered Sugar."

NATURE OF CHARGE: Misbranding (tablets in drum and bottles), Section 502 (a), the labeling of the tablets contained statements which represented and suggested that the tablets were an adequate and effective treatment for dyspepsia, indigestion, gastritis, sour stomach, toxic poisoning, malaria, and general rundown condition, which statements were false and misleading since the tablets were not an adequate and effective treatment for such conditions. The tablets were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: December 29, 1953. The Gottschall Products Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

4498. Misbranding of B-amino-complex tablets. U. S. v. 131 Bottles, etc. (F. D. C. No. 35698. Sample No. 76241–L.)

LIBEL FILED: On or about December 17, 1953, District of Oregon.

ALLEGED SHIPMENT: The tablets were shipped on or about September 14, 1953, by the Landstrom Co., from San Francisco, Calif., and the folders described below were shipped on or about September 7, 1953, by the Unitone Corp., from New York, N. Y.

PRODUCT: 131 bottles of *B-amino-complex tablets* at Portland, Oreg., together with a number of folders entitled "Amazing New Medical Discovery Checks Deafness."

LABEL, IN PART: (Bottle) "100 Tablets B-Amino-Complex * * * A brand of amino acids, coenzymes, vitamins and minerals."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the above-mentioned folders, represented and suggested that the article

was an adequate and effective treatment for deafness, which representations were false in that the article was not an adequate and effective treatment for deafness.

DISPOSITION: June 30, 1954. Default decree of condemnation and destruction.

4499. Misbranding of extract of garlic capsules, wheat germ oil capsules, and WheatonE capsules. U. S. v. 11 Bottles, etc. (F. D. C. No. 33573. Sample Nos. 38627–L, 38628–L.)

LIBEL FILED: September 8, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about May 16 and June 16, 1952, from Jersey City, N. J., and Detroit, Mich.

PRODUCT: 11 100-capsule bottles and 3 400-capsule bottles of *extract of garlic capsules*, 7,900 capsules of *wheat germ oil capsules* in 1 carton, and 62 100-capsule bottles and 11 300-capsule bottles of *WheatonE capsules* at New York, N. Y., in possession of Falkner & May, Inc., together with a number of booklets entitled "Healthful Living Volume Ten 1952," "Healthful Living Volume Eleven 1952," and "Healthful Living 'Highlights' 1952."

RESULTS OF INVESTIGATION: The *extract of garlic capsules* were repackaged from a bulk consignment into bottles and labeled by the consignee, and the *WheatonE capsules* were repackaged by the consignee from portions of an original consignment of 18,000 *wheat germ oil capsules*. The booklets were printed for the consignee and were distributed to customers and prospective customers.

LABEL, IN PART: (Bottle) "Falmay Pure Extract of Garlic in Vegetable Oils"; (carton) "Wheat Germ Oil Ingredients in each capsule: Wheat Germ Oil . . . . 6 Minims"; (bottle) "Falmay sealed 'WheatonE' Capsules contain Hormone Activity plus Natural Vitamin E As Found in Wheat."

NATURE OF CHARGE: *Extract of garlic capsules.* Misbranding, Section 502 (a), certain statements in the booklets entitled "Healthful Living Volume Ten 1952" and "Healthful Living Volume Eleven 1952," which accompanied the article, were false and misleading since the statements represented and suggested that the article would be an adequate and effective treatment for hypertension and nervous stomach, whereas the article would not be effective for such purposes.

Wheat germ oil capsules and *WheatonE capsules.* Misbranding, Section 502 (a), the designation "WheatonE" upon the label of the repackaged capsules was misleading since it represented and suggested that the capsules had tonic properties, whereas the capsules did not have tonic properties. Further misbranding, Section 502 (a), the statements in the booklet entitled "Healthful Living Volume Ten 1952," accompanying the article, namely, "Although the need for hormones and Vitamin E in human nutrition has not been officially established, enough is known of the latter, as a result of experiments on animals, to permit the statement that it is one of the most important of all vitamins. To animal men, Vitamin E is known as the antisterility vitamin, the element that has a great deal to do with the glandular life of animals" were misleading as applied to the *wheat germ oil capsules* and *WheatonE capsules*, which were intended for consumption by man. The statements represented and suggested that there was reason to believe that vitamin E is important to humans, that vitamin E possesses antisterility properties when consumed by humans, and that vitamin E produces important effects on the glandular life of humans, whereas such is not the case.

The articles were alleged to be misbranded in the above respects while held for sale after shipment in interstate commerce. The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: October 8, 1952. Default decree of condemnation and destruction.

4500. Misbranding of It-Sa-Mazing wrinkle lotion. U. S. v. 5 Bottles, etc. (F. D. C. No. 36519. Sample No. 79655–L.)

LIBEL FILED: May 4, 1954, District of Nevada.

ALLEGED SHIPMENT: On an unspecified date, by E. C. Coolidge, doing business as It-Sa-Mazing Products, from Sacramento, Calif.

PRODUCT: 5 8-ounce bottles, 4 4-ounce bottles, and 2 2-ounce bottles of *It-Sa-Mazing wrinkle lotion* at Reno, Nev., together with a number of leaflets designated "Girls 'It-Sa-Mazing' Wrinkle Lotion For That Young Look" and a window display card reading " 'It-Sa-Mazing' For That Young Look Inquire Here For Lotion Guaranteed To Make Your Wrinkles Disappear Or Your Money Refunded."

Analysis showed that the product was essentially a colored and perfumed gum solution.

LABEL, IN PART: (Bottle) "It-Sa-Mazing Wrinkle Lotion For That Young Look Start Now to prevent or eliminate wrinkles * * * This lotion feeds the underlying tissues and tightens the skin."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the above-mentioned bottle label and on the above-mentioned leaflet and window display card were false and misleading. The statements represented and suggested that the article would prevent and eliminate wrinkles, eliminate pimply skin, and feed the underlying skin tissues, whereas the article would not be effective for such conditions and purposes.

DISPOSITION: June 22, 1954. Default decree of condemnation and destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

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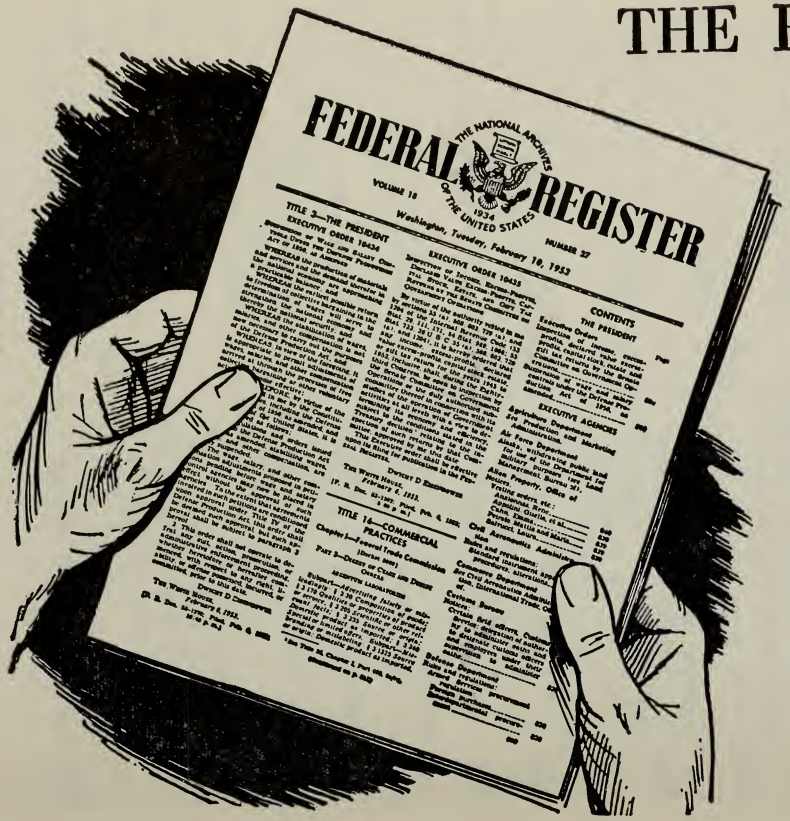

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4501–4520

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *October 25, 1955.*

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359054—55

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4501. (F. D. C. No. 36572. S. Nos. 17–647 L, 17–650 L.)

INFORMATION FILED: 10–4–54, S. Dist. Calif., against **George A. Henry, t/a Henry's Drug Store, Cypress, Calif.**

CHARGE: Between 8–4–53 and 8–24–53, *methamphetamine hydrochloride tablets* were dispensed twice (counts 1 and 2) upon requests for prescription refills without obtaining authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 12–16–54. $350 fine and probation for 1 year on count 1; sentence suspended on count 2.

4502. (F. D. C. No. 35827. S. Nos. 65–736/41 L.)

INFORMATION FILED: 6–4–54, N. Dist. Ill., against **Clifford J. Huston (pharmacist for Wallyn Drugs, Inc.), Chicago, Ill.**

CHARGE: Between 11–17–53 and 12–1–53, *secobarbital sodium capsules* were dispensed 3 times and *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 9–21–54. $600 fine, plus costs.

4503. (F. D. C. No. 35839. S. Nos. 69–532/33 L, 69–535/36 L, 69–542 L.)

INFORMATION FILED: 8–4–54, Dist. Utah, against **Francis E. Cowley, t/a the Cowley Drug Store, Salt Lake City, Utah, and Theodore Paul Christensen (pharmacist).**

CHARGE: Between 9–23–53 and 10–4–53, *methyltestosterone tablets* were dispensed 3 times and *secobarbital sodium capsules* were dispensed once upon requests for prescription refills without obtaining authorization by the prescribers.

PLEA: Guilty—by Cowley to all 4 counts and by Christensen to 2 counts.

DISPOSITION: 10–7–54, Cowley—$1,200 fine and sentence of 3 months in jail to be suspended upon payment of fine; 10–27–54, Christensen—$50 fine and probation for 1 year.

4504. (F. D. C. No. 35818. S. Nos. 58–984/86 L.)

INFORMATION FILED: 6–4–54, N. Dist. Ill., against **William Sonkin (manager of the Meyer Drug & Truss Co.), Chicago, Ill.**

CHARGE: Between 6–21–53 and 7–27–53, *methyltestosterone tablets* were dispensed twice and *apiol capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–28–54. $600 fine, plus costs.

4505. (F. D. C. No. 36615. S. Nos. 69–904 L, 69–912 L, 85–434 L.)

INFORMATION FILED: 7–16–54, Dist. Colo., against **Frank Onufrock, t/a the Aley Drug Co., Colorado Springs, Colo., and Jess Garvin and Harold W. Dozier (pharmacists).**

CHARGE: Between 11–13–53 and 12–2–53, *dextro-amphetamine sulfate tablets* were dispensed twice (counts 1 and 2) and *methyltestosterone tablets* were dispensed once (count 3) upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty—by Onufrock to counts 1, 2, and 3, by Garvin to counts 1 and 3, and by Dozier to count 2.

DISPOSITION: 9–15–54. Onufrock—$1,500 fine and probation for 3 years; Garvin—$500 fine and probation for 1 year; Dozier—$500 fine and probation for 2 years.

4506. (F. D. C. No. 36589. S. Nos. 69–913 L, 69–916 L, 85–433 L.)

INFORMATION FILED: 7–16–54, Dist. Colo., against **Earl Pitcock (a partner in the partnership of Pitcock's Rexall Drug Store), Manitou Springs, Colo.**

CHARGE: Between 12–1–53 and 12–9–53, *methyltestosterone tablets* were dispensed once and *dextro-amphetamine sulfate tablets* were dispensed twice upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 9–1–54. $1,000 fine and probation for 3 years.

4507. (F. D. C. No. 36581. S. Nos. 17–430 L, 17–435/36 L, 17–606 L, 17–623 L.)

INFORMATION FILED: 10–4–54, S. Dist. Calif., against **Lyle L. Bonham (a partner in the partnership of Bonham's Pharmacy), San Diego, Calif., and Harry Laverne Rife (a pharmacist).**

CHARGE: Between 4–1–53 and 6–9–53, *methyltestosterone tablets* were dispensed once (count 3) without a prescription, and *methamphetamine hydrochloride tablets* were dispensed twice (counts 1 and 4) and *dextro-amphetamine sulfate tablets* were dispensed twice (counts 2 and 5) upon requests for prescription refills without obtaining authorization by the prescribers.

PLEA: Nolo contendere—by Bonham to counts 1 and 4 and by Rife to counts 2, 3, and 5.

DISPOSITION: 11–9–54, Bonham—$400 fine; 11–15–54, Rife—$300 fine.

4508. (F. D. C. No. 36638. S. Nos. 81–933/34 L, 81–936 L.)

INFORMATION FILED: 11–18–54, Dist. Nebr., against **Thygesons' Drug Store (a partnership), Nebraska City, Nebr., and Robert W. Thygeson (a partner).**

CHARGE: Between 4–6–54 and 4–8–54, *dextro-amphetamine sulfate tablets* were dispensed twice and *pentobarbital sodium capsules* were dispensed once upon requests for prescription refills without obtaining authorization by the prescribers.

PLEA: Nolo contendere by each defendant.

DISPOSITION: 12–16–54. Partnership—$225 fine, plus costs; Robert W. Thygeson—$150 fine.

4509. (F. D. C. No. 35831. S. Nos. 83–485/86 L, 83–491/92 L.)

INFORMATION FILED: 10–15–54, S. Dist. Iowa, against **Elmer F. Burkhardt, t/a Elmer Burkhardt Drug Store, Burlington, Iowa.**

CHARGE: Between 10–27–53 and 11–11–53, *dextro-amphetamine sulfate tablets* and *pentobarbital sodium capsules* were dispensed once and *thyroid tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11–29–54. $400 fine, plus costs.

4510. (F. D. C. No. 36606. S. Nos. 48–176/78 L.)

INFORMATION FILED: 12–7–54, E. Dist. La., against **George G. Griffon, Jr. (a pharmacist at Griffon's Drug Store), Baton Rouge, La.**

CHARGE: Between 2–8–54 and 2–25–54, *Dexedrine Sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 12–15–54. $300 fine.

4511. (F. D. C. No. 36600. S. Nos. 85–011/12 L, 85–019/20 L, 85–033/34 L, 85–049/50 L.)

INFORMATION FILED: 9–30–54, Dist. Del., against **Park Pharmacy (a partnership), Wilmington, Del., and Milton Salkind (a partner).**

CHARGE: Between 11–25–53 and 12–17–53, *Dexedrine Sulfate tablets* were dispensed 4 times and *phenobarbital tablets* were dispensed 4 times upon requests for prescription refills without obtaining authorization by the prescribers.

PLEA: Nolo contendere by each defendant.

DISPOSITION: 11–12–54. Partnership—$400 fine; Salkind—imposition of sentence suspended and probation for 2 years.

4512. (F. D. C. No. 36590. S. Nos. 49–698 L, 50–680 L, 50–682 L, 50–687/88 L.)

INFORMATION FILED: 7–15–54, Dist. N. J., against **Bernhard Marmerstein, t/a Ben Mar Drugs & Cosmetics, Freehold, N. J.**

CHARGE: Between 1–8–54 and 1–21–54, *Seconal Sodium capsules* were dispensed once and *capsules containing dextro-amphetamine sulfate* were dispensed twice without a prescription, and *thyroid tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9–24–54. $500 fine and probation for 3 years. As a part of the probation, the defendant was ordered to furnish all records concerning the operation of his pharmacy to the Food and Drug Administration on request during reasonable hours.

4513. (F. D. C. No. 36642. S. Nos. 85–127/28 L, 85–132/33 L, 85–143/44 L.)

INFORMATION FILED: 8–27–54, Dist. N. J., against **Joseph Silberman, t/a the Royal Drug Co., Camden, N. J.**

CHARGE: Between 11–3–53 and 11–19–53, *Seconal Sodium capsules* were dispensed 3 times and *cortisone acetate tablets* were dispensed 3 times upon requests for prescription refills without authorization by the prescribers.

PLEA: Nolo contendere.

DISPOSITION: 11–5–54. $250 fine and probation for 3 years.

4514. (F. D. C. No. 35773. S. Nos. 76–151/55 L.)

INFORMATION FILED: 3–10–54, W. Dist. Wash., against **George L. Sorensen, t/a Sorensen's Pharmacy, Seattle, Wash., and Paul L. Owen (an employee).**

CHARGE: Between 7–7–53 and 7–30–53, *Seconal Sodium capsules* were dispensed 4 times (counts 1, 2, 3, and 5) and *capsules containing pentobarbital sodium and carbromal* were dispensed once (count 4) upon requests for prescription refills without obtaining authorization by the prescribers.

PLEA: Nolo contendere—by Sorensen to all counts and by Owen to counts 2 and 5.

DISPOSITION: 8–6–54, Sorensen—6 months in prison and $1,000 fine; 6–3–54, Owen—$300 fine and probation for 5 years.

4515. (F. D. C. No. 36570. S. Nos. 65–731/32 L, 65–734/35 L, 65–750/51 L.)

INFORMATION FILED: 7–15–54, N. Dist. Ill., against **Higgins Pharmacy, Inc., Chicago, Ill., and Ralph A. Higgins (president) and Donald G. Higgins (apprentice pharmacist).**

CHARGE: Between 11–18–53 and 12–3–53, *capsules containing pentobarbital sodium and carbromal* were dispensed 3 times (counts 1, 2 and 3), *amphetamine sulfate tablets* were dispensed twice (counts 4 and 6), and *secobarbital sodium capsules* were dispensed once (count 5) without a prescription.

PLEA: Guilty—by corporation to all counts, by Ralph A. Higgins to counts 1, 3, and 6, and by Donald G. Higgins to counts 2, 4, and 5.

DISPOSITION: 10–13–54. $500 fine, plus costs, against each of the 3 defendants.

4516. (F. D. C. No. 36612. S. Nos. 63–242 L, 63–263/64 L, 63–273 L, 63–278 L.)

INFORMATION FILED: 11–8–54, W. Dist. Mo., against **Randall A. Greer, t/a the Randall A. Greer Rexall Store, Anderson, Mo.**

CHARGE: Between 1–12–54 and 3–1–54, *troches containing a mixture of crystalline potassium penicillin G and bacitracin* were dispensed once without a prescription, and *pentobarbital sodium capsules* and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were each dispensed twice upon requests for prescription refills without obtaining authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 11–26–54. $500 fine.

4517. (F. D. C. No. 36628. S. Nos. 85–481 L, 85–633 L.)

INFORMATION FILED: 11–16–54, Dist. N. Mex., against **Harold N. Harkness, t/a the Harkness Drug Store, Albuquerque, N. Mex., and Ben Jaramillo (pharmacist).**

CHARGE: On or about 12–15–53 and 12–16–53, *secobarbital sodium capsules* and *pentobarbital sodium capsules* were each dispensed once upon requests for prescription refills without obtaining authorization by the prescribers.

PLEA: Nolo contendere—by Harkness to dispensing *secobarbital sodium capsules* and by Jaramillo to dispensing *pentobarbital sodium capsules.*

DISPOSITION: 12–9–54. $150 fine against each defendant.

4518. (F. D. C. No. 36632. S. Nos. 52–278 L, 52–280 L.)

INFORMATION FILED: 11–8–54, S. Dist. N. Y., against **Harold Goldman, t/a the Heathcote Pharmacy, Scarsdale, N. Y., and Richard Marx (pharmacist).**

CHARGE: Between 1–30–54 and 2–5–54, *Sulfose tablets* and *Nembutal Sodium capsules* were each dispensed once upon requests for prescription refills without obtaining authorization by the prescribers.

PLEA: Guilty—by Goldman to dispensing *Sulfose tablets* and by Marx to dispensing *Nembutal Sodium capsules.*

DISPOSITION: 11–24–54. Goldman—$100 fine; Marx—$25 fine.

4519. (F. D. C. No. 36634. S. Nos. 64–987 L, 83–413 L, 83–426 L.)

INFORMATION FILED: 10–28–54, Dist. N. Dak., against **John E. Vardsveen (manager of the Saunders Drug Co.), Minot, N. Dak.**

CHARGE: Between 10–21–53 and 11–19–53, *sulfadiazine tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–4–54. $300 fine.

4520. (F. D. C. No. 36636. S. Nos. 78–690 L, 86–591 L.)

INFORMATION FILED: 12–3–54, S. Dist. Ohio, against **George C. Mitchell, t/a Mitchell's Pharmacy, Cincinnati, Ohio.**

CHARGE: Between 2–15–54 and 2–17–54, *methoxyphenamine tablets* and *paraldehyde* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–3–54. $500 fine.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1955

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4521–4540

DRUGS AND DEVICES

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Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *November 22, 1955.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

4521. (F. D. C. No. 36631. S. Nos. 78–650 L, 78–674/75 L, 78–875 L.)

INFORMATION FILED: 10–18–54, E. Dist. Ky., against **Fayette Ardery, Jr., (pharmacist for the Ardery Drug Co.), Paris, Ky.**

CHARGE: Between 10-22-53 and 1-13-54, *sulfisoxazole tablets* and *thyroid tablets* were each dispensed once and *dextro-amphetamine sulfate capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 1-10-55. $400 fine, plus costs.

4522. (F. D. C. No. 37183. S. Nos. 67–319 L, 67–734/36 L, 67–740 L.)

INFORMATION FILED: 1–13–55, S. Dist. Ala., against **Tom L. Moore, (president of Moore's Pharmacy, Inc.), Mobile, Ala., and Ralph E. Voltes (pharmacist).**

CHARGE: Between 4-1-54 and 4-8-54, *dextro-amphetamine sulfate tablets* were dispensed 4 times (counts 1, 2, 3, and 4) and *penicillin tablets* were dispensed once (count 5) without a prescription.

PLEA: Guilty—by Moore to all counts and by Voltes to counts 1 and 3.

DISPOSITION: 1-24-55. Moore—$500 fine, of which $400 was remitted and the remaining $100 paid; Voltes—$100 fine, which was remitted.

4523. (F. D. C. No. 37180. S. Nos. 48–149 L, 67–326 L, 67–732 L, 67–738 L.)

INFORMATION FILED: 1–13–55, S. Dist. Ala., against **Harold A. Chapman, t/a Davis Ave. Pharmacy, Mobile, Ala., and Robert W. Baird (pharmacist).**

CHARGE: Between 3-26-54 and 4-8-54, *penicillin tablets* were dispensed 4 times (counts 1, 2, 3, and 4) without a prescription.

PLEA: Guilty—by Chapman to all counts and by Baird to counts 1 and 3.

DISPOSITION: 1-24-55, Chapman—$500 fine, of which $400 was remitted and $100 paid; 1–25–55, Baird—$100 fine, which was remitted.

4524. (F. D. C. No. 37168. S. Nos. 85–015/16 L, 85–031/32 L, 85–045 L, 85–047 L, 85–149/50 L.)

INFORMATION FILED: 9–30–54, Dist. Del., against **Bartley Drug Store (a partnership), Wilmington, Del., and Italo R. Debartolomeis and Salvatore Leoncavallo (partners).**

CHARGE: Between 11-25-53 and 12-17-53, *Dexedrine Sulfate tablets* were dispensed 4 times (counts 1 to 4, incl.) and *phenobarbital tablets* were dispensed 4 times (counts 5 to 8, incl.) upon requests for prescription refills without authorization by the prescribers.

PLEA: Nolo contendere—by partnership to counts 1 to 8, incl.; by Debartolomeis to counts 2, 3, 6, and 7; by Leoncavallo to counts 1, 4, 5, and 8.

DISPOSITION: 11-12-54. Partnership—$400 fine; individual defendants—imposition of sentence suspended and each placed on probation for 2 years.

4525. (F. D. C. No. 36673. S. Nos. 52–295 L, 89–092 L, 89–094 L, 89–096 L.)

INFORMATION FILED: 12–28–54, S. Dist. N. Y., against **Grabel's Pharmacy, Inc., New Rochelle, N. Y., and Theodore Grabel (vice president and pharmacist of the corporation).**

CHARGE: Between 1–20–54 and 2–16–54, *Seconal Sodium capsules* were dispensed 3 times (counts 1, 2, and 3) and *sulfose tablets* were dispensed once (count 4) by the refilling of prescriptions without authorization by the prescribers.

PLEA: Guilty by each defendant.

DISPOSITION: 2–4–55. $750 fine against defendants jointly on count 1: imposition of sentence on counts 2, 3, and 4 suspended and individual defendant placed on probation for 6 months.

4526. (F. D. C. No. 36661. S. Nos. 78–693 L, 79–371/73 L.)

INFORMATION FILED: 12–27–54, E. Dist. Tenn., against **Boyd Drug Co., Inc., Greeneville, Tenn., and Edmund G. Sanders (secretary-treasurer and manager of the corporation).**

CHARGE: On or about 3–4–54, *phenylbutazone tablets*, *methantheline bromide tablets*, *dextro-amphetamine sulfate tablets*, and *dextro-amphetamine sulfate capsules* were each dispensed once without a prescription.

PLEA: Guilty by each defendant.

DISPOSITION: 2–11–55. $600 fine.

4527. (F. D. C. No. 37198. S. Nos. 63–669 L, 63–697/98 L, 89–431/32 L.)

INFORMATION FILED: 1–10–55, S. Dist. Ill., against **Goodwin Drug Store, Inc., Peoria, Ill., and William R. Tervehn (vice president and pharmacist of the corporation).**

CHARGE: Between 5–18–54 and 6–23–54, *tablets containing a mixture of sulfathiazole, sulfadiazine, and sulfamerazine* were dispensed once without a prescription; and *secobarbital sodium capsules* and *amphetamine sulfate tablets* were each dispensed twice upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty by each defendant.

DISPOSITION: 1–12–55. $500 fine against each defendant, plus costs.

4528. (F. D. C. No. 37185. S. Nos. 83–465 L, 83–699 L, 88–474 L.)

INFORMATION FILED: 2–17–55, W. Dist. Wis., against **William R. Kruschwitz, t/a "K" Pharmacy, Ashland, Wis.**

CHARGE: Between 3–8–54 and 3–11–54, *dextro-amphetamine sulfate tablets* were dispensed once and *secobarbital sodium capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 2–21–55. $300 fine.

4529. (F. D. C. No. 36605. S. Nos. 70–762 L, 71–105 L, 71–110 L, 78–755 L.)

INFORMATION FILED: 8–31–54, N. Dist. Ohio, against **William D. Foulk (a pharmacist for Foulk's Pharmacy), Bucyrus, Ohio.**

CHARGE: Between 7–21–53 and 10–10–53, *Seconal Sodium capsules* were dispensed 4 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9–17–54. $100 fine.

4530. (F. D. C. No. 36644. S. Nos. 78–886 L, 86–593 L.)

INFORMATION FILED: 12–3–54, S. Dist. Ohio, against **Louis Evans, t/a Highland Pharmacy, Cincinnati, Ohio.**

CHARGE: Between 2–15–54 and 2–24–54, *methantheline bromide tablets* and *phenylbutazone tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–10–54. $150 fine.

4531. (F. D. C. No. 36611. S. Nos. 17–432 L, 17–627 L.)

INFORMATION FILED: 12–27–54, S. Dist. Calif., against **Abraham Bronstone, t/a American Cut Rate Drug Co., San Diego, Calif., and Samuel B. Azhderian and William R. Canfield (pharmacists).**

CHARGE: Between 5–19–53 and 6–5–53, *methyltestosterone tablets* were dispensed once without a prescription and once upon a request for a prescription refill without authorization by the prescriber.

PLEA: Nolo contendere—by Bronstone to each charge of dispensing; by Azhderian to the charge of dispensing without a prescription; by Canfield to the charge of dispensing the unauthorized prescription refill.

DISPOSITION: 3–22–55. $200 fine against each defendant.

4532. (F. D. C. No. 35749. S. Nos. 14–665 L, 69–275 L.)

INFORMATION FILED: 12–54–53, Dist. Colo., against **University Park Medical Clinic Pharmacy (a partnership), Denver, Colo., and Jake DeGarmo (pharmacist).**

CHARGE: Between 12–26–52 and 1–2–53, *pentobarbital sodium capsules* and *secobarbital sodium capsules* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by each defendant.

DISPOSITION: 8–18–54. Partnership fined $1,000; individual placed on probation for 3 years.

4533. (F. D. C. No. 35586. S. Nos. 75–720/1 L.)

INFORMATION FILED: 9–9–54, Dist. Col., against **Morris H. Yarmack, Washington, D. C.**

CHARGE: On 6–17–54, *ergot capsules* and *ergot liquid* were dispensed without a prescription.

PLEA: Guilty.

DISPOSITION: 10–4–54. $300 fine.

4534. (F. D. C. No. 35768. S. Nos. 58–978 L, 58–980 L, 65–711/14 L.)

INFORMATION FILED: 4–14–54, N. Dist. Ill., against **Irving Richter (pharmacist for Pauker's Pharmacy), Chicago, Ill.**

CHARGE: Between 6–4–53 and 6–30–53, *methylparafynol capsules* and *dextroamphetamine sulfate tablets* were each dispensed once and *secobarbital sodium capsules* and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4–5–55. $300 fine, plus costs.

4535. (F. D. C. No. 35829. S. Nos. 61–604/08 L, 81–645 L.)

INFORMATION FILED: 5–21–54, W. Dist. Mo., against **George W. Spengler t/a Spengler Pharmacy, St. Joseph, Mo., and Thomas G. Skinner (pharmacist).**

CHARGE: Between 11–14–53 and 1–12–54, *pentobarbital sodium capsules* were dispensed once (count 1) and *dextro-amphetamine sulfate tablets* were dispensed 5 times (counts 2, 3, 4, 5, and 6) upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by Spengler to all 6 counts and by Skinner to counts 1, 2, 3, and 4.

DISPOSITION: 9–20–54. $505 fine against Spengler and $253 fine against Skinner.

4536. (F. D. C. No. 36593. S. Nos. 64–986 L, 64–989 L, 64–990 L, 65–450 L.)

INFORMATION FILED: 7–26–54, Dist. N. Dak., against **Harry G. Schiefer, t/a Schiefer's Drug Store, Kenmare, N. Dak.**

CHARGE: Between 10–20–53 and 10–23–53, *sulfadiazine tablets* and *dextro-amphetamine sulfate tablets* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 8–2–54. $100 fine.

4537. (F. D. C. No. 35592. S. Nos. 61–220/1 L, 61–223 L.)

INFORMATION FILED: 10–27–54, W. Dist. Mo., against **Harold J. Waugh, t/a Waldo Pharmacy, Kansas City, Mo.**

CHARGE: Between 2–13–54 and 3–3–54, *Dexedrine Sulfate tablets* were dispensed twice and *Donnatal tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–29–54. $252 fine.

4538. (F. D. C. No. 35589. S. Nos. 64–979 L, 83–361 L.)

INFORMATION FILED: 9–22–54, Dist. Minn., against **Cleon G. Ives, t/a Glenwood Drug Store, Minneapolis, Minn., and Wm. A. Hargesheimer (pharmacist).**

CHARGE: Between 10–2–53 and 10–30–53, *secobarbital sodium capsules* were dispensed once without a prescription and *chloromycetin capsules* were dispensed once upon request for a prescription refill without obtaining authorization by the prescriber.

PLEA: Guilty—by Ives to dispensing both drugs and by Hargesheimer to dispensing the *secobarbital sodium capsules.*

DISPOSITION: 12–13–54. Each defendant placed on probation for 2 years; Ives fined $500.

4539. (F. D. C. No. 36633. S. Nos. 42–989 L, 52–301/3 L, 52–981/3 L, 52–988 L.)

INFORMATION FILED: 11–9–54, S. Dist. N. Y., against **Harry Sukenik, t/a Madison Pharmacy, N. Y., N. Y., and Louis Starkhand and Abraham Eastman (pharmacists).**

CHARGE: Between 10–22–53 and 12–11–53, *dextro-amphetamine sulfate tablets* were dispensed 5 times (counts 1, 2, 3, 6, and 7) without a prescription; and *Gantrisin tablets* were dispensed twice (counts 4 and 5) and *Combisul tablets* were dispensed once (count 8) by the refilling of prescriptions for such tablets without authorization by the prescribers.

PLEA: Guilty—by Sukenik to counts 1 to 8, incl.; by Eastman to counts 4 and 5; and by Starkhand to count 1.

DISPOSITION: 12–2–54, Sukenik fined $500; 12–9–54, Eastman and Starkhand fined $50 and $25, respectively, and each placed on probation for 1 day.

4540. (F. D. C. No. 36587. S. Nos. 76–196/98 L.)

INFORMATION FILED: 8–30–54, Dist. Oreg., against **Ray A. Wiener, t/a Hillcrest Pharmacy, Portland, Oreg.**

CHARGE: Between 1–21–54 and 2–1–54, *Seconal Sodium capsules* were dispensed 3 times upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 10–18–54. $1,000 fine.

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